EXHIBIT 7

Lebwohl-18, List of Search Terms, was marked for identification.)

- - -

THE WITNESS: Thank you.

BY MR. MURPHY:

Q. And my question to you, Dr. Lebwohl, is, if you were seeking to query an adverse event database for suggestion of sprue-like enteropathy and olmesartan-associated enteropathy, would you consider these search terms to be adequate?

MR. SLATER: Objection.

You can answer.

THE WITNESS: I'm going to look through the list and I'll ask first for a clarification. Are there items on here that I think should be off or are there items that are not on here that I think should be on?

MR. MURPHY: With regard to the items that are there, you can first tell me whether there are

any that you believe ought not be on.

THE WITNESS: In terms of the FDA looking for adverse events associated with drugs?

MR. MURPHY: Well, not necessarily FDA. I mean --

THE WITNESS: Anyone.

MR. MURPHY: -- a researcher like yourself who might be looking into this question.

THE WITNESS: I think it depends a bit on how sensitive versus how specific one wants to be. Is the question do you want to cast the widest net possible so that you can pick up early signals or is the question that you want to minimize noise and really only focus on the signal, at which point, we're sure to be missing some patients with more atypical or different kinds of signals?

So I think the first

question I would ask certainly as a researcher is, well, do we want to maximize sensitivity or specificity, do we want to capture as many as possible and then worry about weeding out others later, or do we really only want to identify the tip of the iceberg at the beginning?

So I think that's an important question at the foundation.

BY MR. MURPHY:

Q. Assuming that we're beyond tip of the iceberg.

A. If the question is do I want to capture as many patients with olmesartan enteropathy or this kind of clinical phenotype as possible --

Q. Yes.

A. -- then I would worry less about being overly inclusive and add others. I also would take issue with the spelling and specific use of some of

these terms and I can go over these with you if you'd like.

Q. Okay.

A. So, for example, abnormal feces, certainly a feature, not a necessary feature, but certainly a feature. Feces can be spelled in two different ways.

Change of bowel habit is one way to put it, but change in bowel habit is another; and, also, habit is often plural, so I'd probably use a combination Boolean expression to allow for all of those.

Coeliac disease is one of these conditions that has a few different names; and so this one condition, the one spelling is appropriate, but I would consider also searching for it without the O in the word celiac. With the O is more of a British spelling.

I'd also consider celiac sprue. I'd also consider gluten sensitive enteropathy and I would also

Page 362

consider nontropical sprue. These are all terms that are interchangeable and are used by different people to mean really the same entity.

Defecation urgency, I would again consider spelling defecation differently. The same goes for diarrhea. There's an O in there and I would consider taking it out as well.

Enteritis, I don't take issue with someone with olmesartan enteropathy could have enteritis, but what about enteropathy? I don't see it here and I would certainly add it.

Enterocolitis seems appropriate given the enteropathy we know is associated with olmesartan and also the fact that many patients have microscopic colitis.

Fecal incontinence can be a feature of olmesartan enteropathy, so I would look for it with a mind that there's more than one way to spell fecal.

Page 363

Frequent bowel movements is -- it is what it is. Gastrointestinal seems appropriate. Malabsorption, given the caveats we discussed above, is a term that I'm not crazy about, but if I want to cast a wide net and I don't want to just try to find the tip of the iceberg, I would keep it in.

Intestinal villi atrophy, I think, is not a great way to search. I would prefer intestinal villous atrophy or just villous atrophy. Villous can be spelled in a couple of different ways, V-I-L-L-U-S and V-I-L-L-O-U-S. Welcome to my world. Right?

Fecal volume increased, again, I would respell fecal. Gastrointestinal hypermotility is not something that is commonly used, but it seems appropriate.

Diabetic enteropathy is something that I would consider keeping in simply because so many people who take olmesartan happen to be diabetics and

Page 364

they might be misdiagnosed of having an enteropathy due to diabetes as opposed to olmesartan, so I would put it in there.

Protein-losing gastroenteropathy is a feature, not necessarily the only feature, and I would include that, same goes for gastrointestinal inflammation. And intestinal mucosal atrophy seems fine, but I would include some others.

Can I add what I think might be helpful?

Q. Yeah, please do.

A. To start, microscopic colitis, I think that's an important one given that we know many patients with olmesartan enteropathy share that feature. And then I would use its subtypes, lymphocytic colitis, collagenous colitis.

I would also consider using collagenous sprue given that the first time olmesartan enteropathy was reported in the literature was in the context of

Page 365

that condition.

Let's see if there are others that I can continue to look for. I think vomiting is an important one, nausea, vomiting, diarrhea. I would certainly look for that. Many patients have those symptoms.

I don't see abdominal pain. I'm not sure why it was left off there, but I would consider looking there.

I would look for specifically refractory celiac disease because so many patients with olmesartan enteropathy are initially misdiagnosed as having refractory celiac disease.

In that vein, I would consider using those other terms that have been used throughout the day, for example, seronegative villous atrophy, unclassified sprue, just sprue for short. That would be another way to capture some more.

I think dehydration would be an appropriate thing to look for and I

Page 366

don't see it on this list.

I think if we want to cast a net and try to find as many as we can, those off the top of my head would be the list of search terms I'd start out by looking at, but it's very possible that there are some that don't come readily to mind that would also be manifestations, features of olmesartan enteropathy that I would include when doing my own search of associations with olmesartan.

MR. MURPHY: I thank you for going through that and those are my questions, Doctor. I thank you for your time.

THE WITNESS: Thank you.

MR. SLATER: Okay. I just need a couple minutes and then we'll come back in.

(A recess was taken from 6:17 p.m. to 6:32 p.m.)

- - -

EXAMINATION

- - -

Page 367

BY MR. SLATER:

Q. Doctor, you were asked during your testimony about presentations of olmesartan enteropathy less than one year after initiating the drug versus those after two years and were asked some questions about that earlier in the deposition.

My question is this: Do you have an opinion as to whether or not the mechanism for why the person's symptoms are being generated would be any different where somebody's symptoms have an onset in less than a year versus those who are two or more years later?

A. My opinion is that the mechanisms should be the same. They are the same regardless of the duration.

Q. Looking at the last page of your report, if you have that nearby --

A. Here it is.

Q. -- you were asked a little bit about it and I think you wanted to just express something about the quote to

Page 368

Talley, T-A-L-L-Y (sic), I guess it is, about the -- what you cited there.

And if you could, can you tell us what the quote is that you cite in your report and then tell us what the significance of that is from your perspective and why you added that into your report?

A. Sure.

Q. Or included that in your report, I should say?

A. Sure. This was a commentary on the study by Basson and colleagues that we discussed earlier today and it's by Nicholas Talley, gastroenterologist, and it's published in the Annals of Internal Medicine.

He writes, "The well-conducted database study by Basson and colleagues puts to bed any controversy surrounding the association between the ARB olmesartan and severe intestinal enteropathy pathologically resembling celiac disease."

Page 369

He goes on to say, "Evidence" surrounding "a causal relation now includes the strength of association, consistent findings, evidence of improvement in most patients after discontinuation, and relapse on drug reintroduction" --

Q. I just want to stop you. You said "evidence surrounding"? Does it say "evidence supporting"?

A. Forgive me. "Evidence supporting a causal relation." Then it goes on.

Thank you.

Q. And why is that of significance to you? Why did you include that in your report?

A. I included it for a couple of reasons: One is, I think it provides a summation of the data that we have to date because it is recent and it incorporates some of the more recent data we have.

But I also include it

Page 370

because it's published in a high-impact journal, by that, I mean high-reputation, prestigious, often-cited journal, the Annals of Internal Medicine, and the language is clear that this issue has really been laid to rest involving any question about causality.

Q. You were asked by counsel to list those articles that state or -- and you answered the question in the context of stand for the proposition of the causal relationship between olmesartan and olmesartan enteropathy and you listed a series of articles.

If you were to go through each article one by one, would you be able to likely identify additional articles?

MR. MURPHY: Objection; form.

You may answer.

THE WITNESS: I'm sure I would identify additional articles if I were to go through it again

Page 371

that I didn't pick up the first time.

BY MR. SLATER:

Q. In fact, on page 22 into 23, you discuss an article by Schiepatti, S-C-H-I-E-P-A-T-T-I, et al, and over to page 23, you quote from that article: "This study supports the causality of the association between olmesartan and enteropathy."

Would that be an example of an article you didn't list earlier, I don't believe, that that would also stand for the proposition? Is that an example of that?

MR. MURPHY: Objection to form.

THE WITNESS: That would be another example.

BY MR. SLATER:

Q. You were asked about the Greywoode article and I just want to be very clear. Even though it did not demonstrate statistical significance of

Page 372

the finding, do you have an opinion, and if you can explain this, as to why that is an important article in the overall question of causation and how it fits into the determination that you've given of causation?

A. A specific aspect of the --

Q. You know what, I'm going to withdraw that question, actually. I want to ask you about something else, actually. I want to ask you a completely different question, actually.

A. Okay.

Q. I think you handled that one for about an hour. I'm not going to go back into it.

Here's my question: You were asked about the so-called hierarchy of different types of studies, RCTs, all those other type studies; and in the context of olmesartan, in identifying and studying the entity of olmesartan enteropathy, can you just give us an explanation of why it is or what your

Page 373

opinion is as to which studies have been most helpful in understanding that entity in the literature?

MR. MURPHY: Objection to form.

You may answer.

THE WITNESS: In fact, it's the case reports with multiple dechallenge and rechallenge in multiple contexts from around the world that are actually most helpful.

There are other study types that we talked about earlier today that have added to the impression, but convincing case reports with well-documented dechallenge and rechallenge data can be the most helpful, despite the fact that in a generic pyramid of evidence, case reports are on the bottom.

In fact, RCTs are not well suited to look at uncommon long-term effects, both because

Page 374

the number of patients in an RCT, for example, the ROADMAP study, is not sufficiently high so as to look for an uncommon effect, nor do they follow patients long enough to look for a long-term adverse effect.

And I should add that even within the ROADMAP study, it turned out that there were patients who had olmesartan enteropathy which was not noted by the authors of that post hoc analysis.

BY MR. SLATER:

Q. And when you say there were patients that were noted that had that, was that based on your review of internal documents that were not publicly shared with the medical community?

A. Yes.

MR. MURPHY: Objection to form.

BY MR. SLATER:

Page 375

Q. You were asked about the variable rates of resolution and timing of resolution, et cetera, of olmesartan enteropathy; and in terms of your opinion, why is that with regard to olmesartan enteropathy?

A. Why do I see that?

Q. Yeah.

A. It's analogous to variable rates of healing we see in celiac disease that include the individual's capacity to heal that will vary from patient to patient and we're likely seeing the same phenomena, those patient-specific variability, in olmesartan enteropathy.

Q. Let's look at the DeGaetani article for a moment.

A. Sure. I got it.

Q. Look, if you could, at table 3. I think that was the famous table 3 we've looked at a few times.

A. I see it.

Q. If we look at table 3, there is a column for biopsy improvement after stopping medication. Do you see that?

A. Yes.

Q. There's a plus sign next to two of the patients which means that improvement was seen; correct?

A. Just two of the patients?

Q. Yeah, if you look down, if you go down that column for the olmesartan patients, there's a plus sign for two of them. Do you see that?

A. Perhaps you can show me.

Q. (Indicating.) In that column (Indicating).

A. Oh, the biopsy column.

Q. Yes.

A. Yes, I see plus signs in two of those patients.

Q. That means there was improvement seen.

A. That's right.

Q. Not applicable is indicated for the rest. Does that mean there just wasn't a biopsy to look at at the time this was published?

Page 376

Page 377

A. That was my understanding, that biopsies were not done.

Q. For those patients. Okay.

Now, with regard to that one patient with the question mark in terms of whether she had clinical improvement, patient number 7 --

A. Yes, I see that.

Q. -- during the course of questioning by counsel, you had talked about the fact that you thought it might be that there was a lack of follow-up data.

If you look at the discussion section, below the discussion at the bottom of the middle column, there's a sentence that says, "Upon discontinuation of this medication, all 15 patients on whom we had follow-up data improved symptomatically, no longer requiring immunosuppressive therapy if they had previously been on it," et cetera.

A. I see that.

Page 377

Page 378

Q. So does that confirm for you that there was a lack of follow-up data on that one patient?
A. Correct.
Q. With regard to the Bradford Hill criteria, did you consider the nine different criteria as you evaluated the evidence that was available to you in forming your opinions in this case?
A. I considered those criteria when I was evaluating the evidence.
Q. Even though you may not have specifically named a few of them, it's your testimony you did consider the entire criteria?
A. Correct.
Q. And I think you mentioned a few of the criteria during the course of your testimony, like cessation of exposure and others, those were criteria you were aware of and applied?
A. Yes.
Q. In the Greywoode article, there is a statement in the article

Page 379

suggesting that milder presentations are unlikely at that time. That's part of the conclusion in the abstract?
A. Yes, it is.
Q. What's your opinion now at this time and at the time you wrote your report in this case as to whether it is likely or unlikely that there are milder presentations of olmesartan enteropathy?
MR. MURPHY: Objection; form.
You may answer.
THE WITNESS: I believe that milder presentations are, in fact, likely.
BY MR. SLATER:
Q. Is that in part based upon review of the literature and the case reports that have been coming out even up till very recent?
A. Correct.
Q. You were asked about internal company documents. And do you and other physicians in the medical

Page 380

community rely on the information companies provide regarding the risks, for example, of medications that they sell?
A. We do.
Q. And to the extent the company has information internally about risks, do you and other doctors expect that that internal information is being shared with you and others in the medical community so you will have that in treating and diagnosing patients?
A. Yes.
MR. MURPHY: Objection to the form; lack of foundation.
THE WITNESS: Yes.
BY MR. SLATER:
Q. With regard to the internal documents that you saw from Daiichi and the deposition testimony you saw regarding the adverse events they were aware of and the internal discussions about them, what was your reaction to that when you saw that?

Page 381

MR. MURPHY: Objection; form.
THE WITNESS: Particularly when I looked at the dates, I was stunned by the dates, in that they happened so far before the general medical community was first apprised of this condition. And I would have loved to know about those cases at the time that they happened, well before the first publications.
I think that my patients would have wanted to and I think that my group, the physicians in the biomedical community, would have wanted that information at that time.
BY MR. SLATER:
Q. And why is that?
A. Given the morbidity that we see in olmesartan enteropathy, the suffering, the diagnostic travails that many people have, the misdiagnosis,

there's hospitalizations and sometimes even worse, if we had known about this entity well before 2012, we could have prevented a good amount of suffering.

Q. And you've seen the adverse event reports and you were asked some questions about them today. Even if Daiichi had just shared information about these symptoms that they were seeing and the syndrome that they were seeing, even if they didn't know what the name of it was and just told doctors, we're seeing multiple patients with these clinical pictures, would that have been helpful to you and of interest to you and other physicians in your field?

MR. MURPHY: Objection to form; lack of foundation.

THE WITNESS: For sure.

BY MR. SLATER:

Q. And is that for the same reasons you just stated?

A. Yes. It also would have helped our research efforts to better

understand this condition.

Q. You were asked at the end of the deposition about search terms. And in the interest of time, I'm just going to ask you if the following terms would also fall into the category of those you would want to include if you were going to cast this wide net to catch relevant reports in the literature.

And in the interest of time, I'm going to list them: sprue-like symptoms, chronic diarrhea, abnormal loss of weight, weight decreased, underweight, anemia, renal insufficiency, renal failure, and steatorrhea, would those be helpful terms as well?

A. Yes.

MR. SLATER: I have no other questions.

MR. MURPHY: I guess we're done subject to resolution of our request for the patient data that I made earlier on the record.

MR. SLATER: Everyone have a

nice weekend.

THE WITNESS: Thank you, everybody.

(Witness excused.)

(Deposition concluded at approximately 6:47 p.m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, BENJAMIN LEBWOHL, M.D., M.S., have the opportunity to read and sign the deposition transcript.

KIMBERLY A. CAHILL, a
Federally Approved Registered
Merit Reporter and Notary Public
Dated: February 13, 2017

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LAWYER'S NOTES

PAGE LINE

WORD INDEX

< 0 >
0.14 158:*21*
003790 340:*18*
05 6:*22* 7:*3* 160:*7* 230:*12* 340:*2* 346:*1*
07068 2:*4*
07932 2:*18*

< 1 >
1 11:*3*, *8* 35:*3* 92:*21*, *24* 109:*6* 157:*13* 158:*10*, *18* 159:*2* 220:*8* 276:*10*
1.99 158:*16*
1:11 140:*6*
10 1:*7* 6:*8*, *8*, *12* 8:*11* 256:*7*, *17* 274:*12*, *18* 307:*9*, *9* 320:*3*
10:36 56:*7*
10:46 56:*7*
100 243:*9*, *12*, *13*, *19*, *24* 244:*5*, *5*
10022 2:*9*
102 238:*24*
103 2:*3* 238:*24*
105 269:*1*, *5*
11 5:*1*, *3* 6:*12* 38:*2*, *3* 42:*18* 43:*14* 81:*23*, *24* 263:*1* 320:*3*
12 271:*3* 276:*13*, *17* 277:*15* 331:*23*
12:25 140:*6*
12:30 139:*24*
1239 267:*12*
129 6:*24* 340:*3*
13 307:*17*, *17* 308:*5*, *21* 318:*6* 385:*15*
130 7:*6* 346:*4*
14 4:*16* 29:*9* 138:*6* 155:*15* 320:*11* 337:*9*
14th 332:*4* 339:*16* 340:*23*
15 4:*21* 6:*8*, *12* 28:*10* 218:*13* 307:*9* 320:*3* 335:*8*, *18* 345:*16* 377:*19*
15-2606 1:*6*
16 5:*1*, *1*, *3* 38:*2*, *2*, *3* 200:*7* 201:*15*, *23* 204:*21*, *23* 205:*2*, *18*, *21* 206:*9*, *21* 209:*1*, *19* 210:*16*, *17* 211:*5* 218:*13* 220:*9* 243:*17*, *17* 277:*24* 278:*1* 339:*21* 340:*13* 343:*5*
160's 335:*24*
164 335:*24*
17 5:*1* 35:*23* 206:*21* 216:*16*, *22* 345:*21*
173 337:*2*, *9*
174 338:*1*
178 5:*10*
18 5:*1* 38:*2* 39:*4* 138:*16* 155:*17* 357:*21*
18th 2:*13* 40:*8*
19 6:*22* 8:*7* 98:*17* 340:*2*
19103 2:*14*
198 8:*11*

< 2 >
2 5:*1* 14:*6*, *18* 35:*3*, *23* 80:*2*, *22* 81:*7* 89:*9* 90:*17*, *23* 91:*1*, *10* 206:*9* 208:*24* 209:*20* 210:*6* 274:*10*, *14* 276:*17*
2:20 199:*13*
2:33 199:*13*
20 222:*2*, *16*, *19*, *24* 273:*1*, *3* 274:*13*, *18* 275:*13*, *21* 276:*1*, *4*, *14*, *17* 277:*15* 311:*3* 320:*21*
200 5:*12*
2000 2:*13*
2005 339:*16* 340:*23* 345:*16* 351:*17*, *18*
2006 309:*24* 310:*2*, *4* 311:*2*
2007 319:*7* 322:*1*
2011 202:*17*, *20* 203:*15*
2012 18:*6* 23:*6* 178:*13* 196:*3* 197:*19*, *22* 214:*15* 245:*11* 283:*13* 313:*14* 348:*11* 355:*23* 382:*3*
2013 5:*12* 57:*10* 138:*13* 161:*13* 200:*21* 209:*6* 210:*3* 214:*11*
2014 5:*10*, *22* 6:*4* 135:*22* 140:*22* 178:*24* 262:*15* 269:*24* 271:*8*
2015 5:*18* 28:*21* 29:*9*, *15*, *21* 30:*6*, *8* 32:*3* 34:*6* 53:*12* 84:*13* 135:*18* 237:*1*, *6*, *22* 255:*23* 310:*3*
2016 6:*18* 28:*2* 37:*10* 40:*10* 42:*18* 43:*14* 44:*12*, *15*, *18* 84:*8*, *14* 335:*12*
2017 1:*7* 97:*23* 385:*15*
20-pound 319:*13*
21 7:*3* 86:*16* 346:*1*
212 2:*9*
215 2:*14*
22 200:*7* 371:*4*
228-9898 2:*4*
22nd 319:*7* 322:*1*
23 5:*1* 38:*2* 40:*8* 42:*17* 84:*3*, *8*, *13* 92:*21* 93:*1* 96:*15* 371:*4*, *7*
23rd 39:*4*
255 5:*18*
26 4:*21* 34:*12*
262 5:*22*
27 147:*6*, *8*, *9*
271 6:*4*
28 4:*21* 224:*21* 241:*3* 250:*24* 254:*10*
28th 39:*8*, *14*
29 5:*3* 38:*3* 39:*4* 40:*9* 85:*6*
2nd 2:*3* 332:*2*

< 3 >
3 28:*7*, *16* 43:*19* 158:*15* 161:*13* 205:*14*, *17* 210:*4* 218:*12* 375:*20*, *20*, *23*
3.1 66:*3*
3:32 254:*7*
3:41 254:*7*
30 37:*19* 161:*18* 162:*13*, *14*
307 6:*8*
31 6:*18* 335:*12* 347:*3*, *10*
32 306:*21*, *22* 307:*19*, *23* 308:*24* 309:*8*
320 6:*12*
325 322:*11*
33 309:*9* 319:*2*, *3*
335 6:*16*
339 6:*19*
34 4:*21* 334:*11*, *12* 335:*22* 336:*5*, *6*, *8*, *11*, *17*, *18*, *21*
3400 1:*16* 2:*8*
346 7:*3*
347 6:*14* 320:*5*
35 5:*1*
358 7:*7*
35-year-old 344:*3*
36 339:*9*, *11* 340:*15* 345:*5*, *7* 347:*8*
367 4:*7*
36-year-old 340:*24*
37 297:*10*, *11* 300:*1*
38 5:*1*

< 4 >
4 29:*9* 34:*9*, *19* 35:*8* 36:*8*, *12*, *15* 81:*14* 180:*10* 275:*13*, *21* 297:*12*
4:34 297:*7*
4:44 297:*7*
40 222:*2*
420 180:*10*
43 47:*2*
44 37:*17*
46 8:*7*

< 5 >

5 4:*21*, *21* 28:*10*, *10* 36:*5*, *8*, *13* 66:*4* 129:*21* 165:*1*, *2* 177:*13*, *14* 313:*18* 320:*23*
5.00 159:*3*
5:09 318:*23*
5:14 318:*23*
50 264:*2* 274:*18*
549-7000 2:*19*
58 345:*16*
58-year-old 347:*1*, *19*
5th 28:*21* 97:*23*

< 6 >
6 37:*23* 38:*20*, *21* 39:*1* 40:*4* 42:*15* 81:*16* 83:*23* 84:*17* 85:*5* 184:*18* 214:*23*
6:17 366:*21*
6:32 366:*21*
6:47 384:*6*
600 2:*18*
601 1:*16* 2:*8*
650 213:*1*, *9*

< 7 >
7 6:*22* 38:*9* 88:*24* 92:*5* 158:*9* 161:*8* 199:*18*, *19* 313:*19* 340:*2* 377:*7*
72 200:*6* 201:*15*
733 245:*16*
749 6:*10* 307:*11* 308:*7*, *10*
79 159:*2*, *11*

< 8 >
8 81:*19* 97:*17* 161:*17* 179:*7* 180:*11* 326:*3*
877.370.3377 1:*22*
88 5:*5*

< 9 >
9 4:*5*, *12* 5:*1*, *1* 7:*3* 35:*23* 38:*2* 134:*5* 276:*1*, *4* 346:*1*
9:45 1:*17*
917.591.5672 1:*22*
95 158:*14*, *16* 159:*6*, *8*
973 2:*4*, *19*
980-7400 2:*9*
988-2700 2:*14*
99 145:*13*

< A >
a.m 1:*17* 56:*7*, *7*
abated 319:*19*
abbreviated 257:*2*
abdominal 6:*6* 53:*8* 110:*1* 237:*9*, *10*, *13* 238:*7* 271:*10* 273:*23* 309:*18* 311:*1*, *13* 312:*11*, *21* 313:*3*, *5* 314:*5*, *11*, *17* 315:*10* 365:*8*
ability 145:*24* 270:*24*
able 113:*19* 189:*12* 193:*7*, *11* 199:*3* 231:*14* 242:*22* 313:*20* 338:*10* 370:*17*
abnormal 123:*5* 361:*4* 383:*12*
abnormalities 78:*23* 192:*21* 253:*16*, *20* 290:*3*
abnormality 171:*15* 274:*1*
abouts 37:*16*
Abrams 93:*19*, *24*
absence 60:*4* 111:*3* 170:*3* 245:*2*, *4* 281:*12* 350:*20*
absolutely 280:*21*
absorb 119:*6*
absorption 259:*18*
Abstract 96:*19*, *22* 97:*3* 113:*13* 267:*14* 270:*16* 273:*20* 302:*10* 379:*3*
abstractions 305:*14*
abundant 123:*14* 254:*23* 301:*6*
academia 270:*22*
accelerate 183:*5*
accelerated 342:*18*
accept 240:*8*
acceptance 335:*3*
accepted 108:*18* 160:*5* 262:*8*
access 16:*9* 329:*24*
accompanied 104:*9*
accompanies 86:*9*
Accompanying 11:*10*
account 94:*15* 100:*17* 243:*2* 294:*22*
accurate 22:*11* 274:*7* 314:*16*
accurately 15:*23* 156:*12* 196:*13* 264:*14* 297:*23*
accusing 161:*20*
achieve 160:*8*, *18* 294:*2*
achieved 159:*21*
acid 265:*17*, *18*
acknowledge 13:*20* 111:*15* 147:*19* 158:*7*
acknowledged 112:*9*
acknowledging 243:*3*
acknowledgment 336:*24*
acknowledgments 335:*2*
acquainted 59:*16*
acronym 231:*2* 234:*5*
action 49:*4*, *20* 50:*11*, *15* 51:*14*, *23* 53:*1*, *19* 56:*10* 57:*14*
activation 259:*12*
active 192:*1* 234:*1*
activities 43:*9*, *12*
activity 259:*11*
actual 36:*21* 162:*9* 269:*17* 278:*13*
acute 66:*24* 171:*1*
acutely 126:*12* 327:*3*
ADAM 2:*3* 27:*13* 82:*9* 105:*15* 131:*10* 235:*9*
add 56:*8* 60:*1* 113:*15* 157:*13* 196:*4* 229:*23* 259:*9* 269:*15* 360:*22* 362:*14* 364:*11* 374:*8*
added 368:*7* 373:*15*
addendum 35:*11* 36:*6*, *18*
addition 12:*11*
additional 33:*19* 88:*6* 112:*13* 161:*11* 321:*24* 370:*17*, *23*
address 49:*20* 63:*16* 88:*9*, *11* 114:*6* 224:*23* 226:*11*, *12* 227:*6*
addressed 44:*3* 51:*15*, *17* 52:*23* 57:*13* 63:*2*
addresses 53:*18* 63:*10*
addressing 28:*4* 50:*10* 51:*13*, *23* 292:*11* 297:*14* 299:*19*
adequate 358:*12*
adequately 230:*18* 233:*24*
adjusted 325:*15*
administrative 229:*15*
admit 163:*8*
adulthood 68:*7* 168:*22*
adults 222:*14* 223:*5*
advance 248:*17*
Adverse 6:*21* 58:*18* 66:*23* 148:*18* 149:*13*, *15* 151:*20* 230:*7*, *17*

231:6, 12, 17 233:4, 13 240:20 241:7 268:5, 16 279:20 283:3 286:18 303:4, 11 304:8, 10, 17 306:4 334:19 337:17 339:15 340:1, 22 345:14 354:6, 13, 15, 24 355:14, 18 356:16, 17 358:8 359:4 374:7 380:21 382:5
advice 29:19 30:1 33:7 63:23
advised 16:8 114:21 191:12 192:7
AERs 240:21 241:18 242:2
affect 127:16
affirmatively 47:21
affirmed 9:8
affordable 151:16
African-American 344:15
afternoon 173:3
age 269:21
agent 143:1, 7 149:12 167:14 176:22
agents 258:24 260:2
aggregate 47:5 60:12, 17, 22 184:6
aggregate, 60:15
ago 24:20 60:10 303:3
agree 29:11 179:22 225:3 244:9 284:23 308:9 323:19 332:12
agreed 27:10 233:12 334:20 351:23
agreed-upon 125:14
agreement 125:5
Ah 303:24
ahead 26:4 38:22 94:20 108:5 137:9 259:2 292:18 325:12 353:15
akin 261:15
al 5:17, 21 6:8 18:1 110:15 115:22, 24 201:1 256:2 271:13 287:10 371:6
alarming 229:19
Al-Bawardy 97:16
Alimentary 135:16, 21
allegation 23:23
alleged 23:18 25:15
Allen 80:19 84:4 323:15 332:13
allergic 67:1
allow 65:20 288:20 296:5 361:13
allowed 49:14
allows 69:3
allusion 79:8
alternate 257:15
alternative 79:12 317:23 318:4 326:9 334:8 344:6
alternatives 317:20
amazing 188:8
ambiguity 249:24
American 57:9
amount 21:4 60:5 126:9 223:10 259:13 269:16 382:4
Amy 3:2
analogies 20:15
analogizing 122:14
analogous 67:21 103:14 121:21 176:14 291:7 296:16 375:9
analogy 226:3, 9
analogy's 290:5
analyses 62:10
analysis 157:2 158:12 201:10 224:16 225:6, 18 231:21 232:14 238:23 239:21 262:3 353:20 374:14
analyze 240:15
analyzing 247:20
anecdotal 284:13, 14 285:18, 20, 22
anecdotally 284:1
anemia 119:9 121:3 383:14
angiotensin 6:7 53:10 54:1 96:15 109:2, 14 110:3 153:11 237:14 251:9 258:5 271:12
angstrom 109:21
animal 59:17, 19, 21, 23 60:1
animals 59:15
Annals 107:16 138:12 368:16 370:4
announcement 161:12 162:10
Annual 96:18
Answer 8:5 10:8 13:19 16:6 20:4 26:13 29:17 30:22 31:10 36:11 45:4 46:6, 19 47:16 48:4, 16 49:24 52:9 56:9 57:18 63:6 70:9 77:9 87:24 88:3 89:21 90:5, 22 92:14 97:12 106:22, 24 124:10 139:17, 18 147:23 150:1 152:20 160:22 161:1 172:14 173:2, 5, 18 174:6 181:14 182:1 190:11 192:3 193:13 194:11 203:4 207:4, 8, 17 208:7, 17 215:7 216:6 217:20 221:11 226:15 227:13 231:9, 14, 19 234:9 235:6 236:4, 12 240:12 249:14 250:1 282:12 287:3 289:5 291:13 292:4 294:10 296:11 302:8 310:12 313:16 314:10 324:21 331:7 346:10 348:4 350:5 357:12 358:14 370:21 373:6 379:12
answered 44:7 45:3 49:23 52:4 55:12 88:2 118:12 160:11, 13 172:16 205:1 233:8 241:24 253:10 296:9 342:20 370:10
answering 15:23 46:21 108:3
antiarrhythmic 327:2, 4
anticipated 284:12
antihypertensive 191:14
Antihypertensives 5:23 140:19 262:17
apart 115:10 141:24
apologies 131:2 172:6
apologize 117:14 120:1
apparent 169:4
appear 66:22 67:3 127:22 253:19 259:5
APPEARANCES 2:1
appeared 216:12 304:2 326:4
appears 34:20 121:9 122:7 128:21 178:16 220:12 223:1 224:5 246:20 256:23 260:16 280:9 288:12 313:6 331:15, 22
apples 247:6
applicability 261:22

applicable 149:*11* 150:*14* 376:*21*
applied 333:*21* 354:*21* 378:*21*
applies 287:*3*
apply 230:*8* 385:*18*
applying 332:*22* 333:*17*
appreciate 21:*13* 163:*5* 252:*17* 267:*10*
appreciated 24:*11*
apprised 381:*8*
approach 37:*4*
approached 27:*16* 29:*12*, *19* 30:*1*, *10* 63:*22* 223:*16*
appropriate 21:*19* 22:*1* 103:*6* 208:*7* 265:*9* 277:*10*, *11* 302:*20* 361:*18* 362:*16* 363:*3*, *20* 365:*24*
appropriately 290:*11*
Approved 1:*18* 301:*3* 385:*14*
approximately 296:*1* 384:*6*
April 29:*14*, *21* 196:*3* 197:*19*, *22* 214:*14*
apriori 248:*3*
ARB 258:*4*, *4*, *11*, *14* 259:*14* 273:*14*, *16* 275:*7*, *9*, *24* 276:*8*, *13*, *18* 277:*8*, *16* 368:*22*
ARBs 229:*16* 267:*18*
architectural 122:*8*
architecture 123:*22*
area 72:*24* 87:*3* 141:*1*
areas 87:*5*
argue 59:*18* 133:*9* 154:*9* 185:*14*
Arguellas-Grande 110:*4*
argumentative 234:*17*, *19* 235:*1*
arm 230:*8*, *10* 239:*23*
Article 6:*4* 19:*5*, *7* 20:*19* 21:*12* 53:*17* 98:*18* 106:*10* 107:*2*, *10* 109:*7* 110:*21* 111:*21* 112:*10*, *21* 133:*11* 134:*8*, *13*, *22* 135:*3*, *5* 137:*1*, *17* 138:*23* 143:*3*, *11*, *13* 145:*2*, *4* 146:*11* 183:*8* 204:*23* 232:*1* 263:*2*, *7* 267:*12* 271:*8* 305:*22* 370:*16* 371:*5*, *7*, *12*, *22* 372:*3* 375:*17* 378:*23*, *24*
articles 21:*8*, *9*, *14* 52:*22* 59:*13* 63:*1* 90:*17* 91:*13* 92:*24* 93:*1*, *15* 95:*20* 99:*18* 103:*7*, *11* 105:*6*, *10* 107:*12*, *23* 108:*7* 112:*19* 113:*1*, *10*, *20* 130:*2*, *10*, *20* 131:*4* 132:*14* 133:*1* 136:*8*, *9* 137:*3* 138:*24* 140:*9* 151:*24* 286:*17* 370:*9*, *14*, *18*, *23*
ascertain 189:*24*
ascertainments 203:*23*
aside 129:*11* 171:*4* 186:*12*
asked 10:*9* 18:*14* 32:*8* 33:*2*, *7*, *16*, *21*, *24* 34:*2* 43:*13* 44:*7*, *21* 45:*3* 47:*18* 49:*23* 64:*9* 77:*12* 88:*1* 102:*24* 118:*7*, *8* 130:*12* 136:*9* 141:*2* 151:*23* 155:*20* 160:*10*, *22* 173:*4*, *6* 174:*13* 194:*4* 207:*9*, *13* 223:*17* 241:*23* 278:*21* 293:*3* 295:*16* 296:*9* 310:*17* 311:*18* 353:*22* 367:*2*, *6*, *22* 370:*8* 371:*21* 372:*18* 375:*1* 379:*22* 382:*6* 383:*2*
asking 10:*10* 24:*4* 32:*13* 63:*22* 66:*7* 83:*5* 98:*8* 107:*9* 108:*1* 124:*2* 132:*24* 150:*24* 170:*14* 173:*9* 175:*8* 204:*7* 217:*21* 219:*5* 233:*6* 238:*2* 253:*7* 255:*17* 258:*21* 268:*15* 277:*21* 291:*2* 295:*13* 300:*8* 310:*15* 341:*7* 356:*24*
asks 11:*11*, *19*
aslater@mskf.net 2:*5*
aspect 223:*23* 320:*13* 372:*7*
aspects 87:*10* 90:*1*
assess 315:*19* 317:*18*
assessing 147:*13* 232:*14*
assessment 190:*20* 245:*5* 316:*13* 323:*20* 324:*12*
assessments 315:*22* 317:*11*
assistance 45:*12*, *21*
Assistant 3:*2*
Associated 5:*11*, *20* 41:*24* 42:*1* 75:*3*, *5* 78:*3* 79:*10* 96:*17* 100:*11* 110:*11* 111:*4* 138:*2* 141:*4* 153:*12* 156:*1* 179:*1* 225:*17* 232:*4* 238:*22* 253:*3* 257:*18* 267:*19*, *22* 268:*4* 322:*16* 323:*2*, *5* 324:*16* 359:*5* 362:*17*
association 111:*6* 114:*16* 115:*7*, *12* 129:*5* 158:*20* 159:*9* 160:*2* 161:*1* 227:*6*, *12*, *17* 228:*2*, *9* 229:*6* 237:*24* 238:*19* 264:*19* 269:*4* 284:*3* 368:*21* 369:*3* 371:*9*
associations 157:*4* 366:*11*
assume 21:*11* 95:*6*, *8*, *12* 114:*11* 250:*4* 292:*7*
assumed 78:*10*
assuming 123:*10* 329:*15*, *18* 337:*3* 352:*2* 360:*14*
assumption 10:*7*
atrial 322:*10* 327:*6*, *8*
Atrophy 5:*14* 51:*9* 57:*1* 68:*1*, *3* 109:*16* 119:*20*, *21* 120:*6*, *8* 121:*18* 122:*2*, *6*, *15*, *19*, *21* 123:*7* 124:*24* 125:*3*, *8*, *15*, *20* 133:*24* 134:*7* 136:*3* 170:*2*, *4*, *10*, *15*, *19*, *22* 171:*3*, *9*, *18* 200:*7*, *22* 201:*17* 204:*9* 205:*8* 214:*8* 247:*23* 252:*2*, *5*, *23* 255:*12* 350:*21* 363:*9*, *11*, *12* 364:*9* 365:*19*
atrophy, 93:*22*
attached 15:*16*
Attaching 6:*22* 7:*4* 340:*2* 346:*3*
attack 101:*7*, *8*, *10*
attempted 291:*24*
attempting 317:*18* 342:*1*
attention 47:*1* 79:*16* 114:*22* 137:*8* 165:*14* 166:*5* 205:*13* 212:*24* 224:*21* 254:*10* 274:*10*

319:2 334:10 335:7
attestations 25:3
attorney 9:17 13:15 24:24 30:9
attorneys 26:11
attribute 201:11 324:5
attributed 200:8 201:6 203:2 205:2
atypical 359:22
author 20:24 57:5 120:15 152:13 153:6 236:22 237:2, 17
authored 237:5
authors 78:13, 24 113:4 146:22 147:3 180:4 221:6 261:1 283:18 286:1 374:13
author's 57:6
autoimmunity 78:20
available 91:18 116:1 134:16 151:21 209:11 260:17 305:19 316:21 317:15 378:8
Avenue 1:16 2:8
aware 21:1 61:1, 3 63:17 82:7 93:23 94:23 95:15, 16 97:20 98:19 99:3, 8 137:4 170:20 221:16 228:22 298:18 299:2 300:20, 22 324:17 354:2 355:24 378:21 380:22
awareness 356:15
axes 100:19 253:13, 20
Aziz 133:4 153:18 155:19
Azor 191:21, 22

< B >
B-12 282:7
back 19:15 35:4 36:24 42:5 48:20 54:10 55:6 66:12 70:14 86:13 90:5 94:1 98:21 106:6 113:2 118:10 139:15 152:5 169:1 171:21 173:3, 13 184:18 189:11 193:4 194:21 195:11, 17 197:5 199:14 208:20 212:22 215:17 249:18 254:10 277:23 292:10 303:8 311:23 316:23 318:17 321:21 324:14 339:3 351:18, 23 352:9 366:19 372:16
background 90:2, 12 95:5, 10 338:8
bad 126:15 292:17
barely 157:17
barrier 69:3
based 52:12 117:11, 16, 19 122:13 128:21 137:17 165:12 168:22 184:9 203:22 217:1 265:11 269:4, 18 279:4 282:16 288:23 306:7 316:21 318:10 331:24 332:11 333:3 334:18 343:22 374:18 379:17
baseline 277:9
basic 261:19
basically 187:24 190:16
basis 50:5 55:15 298:10
baskets 95:5, 14
Basson 75:17 112:14 114:5, 13, 14 115:16, 21, 24 132:1, 3 155:5, 6 227:7, 11, 15, 20 251:2 368:13, 19
Bates 347:3
bathing 258:23
bear 40:14 177:12 216:18
becoming 132:7
bed 368:20
beg 104:18
began 30:18 31:17 32:3 33:19 37:7 42:21 312:16
beginning 1:17 56:22 67:8 114:12 281:6 309:18 360:9
begins 165:6 199:23 278:5
behalf 23:12 32:5
behold 247:21
beings 60:6 259:17
belief 211:11 222:1 240:14
believe 12:8 14:3 19:13 21:7 30:5 35:10 37:9, 14 42:7 43:16, 22 47:18, 19 55:11 64:5 82:17 85:11 89:22 94:22 106:14 108:15 109:22 110:6 111:20 113:24 115:16 120:4 124:7 127:11 129:15 131:19 137:6 146:21 147:3 150:21 152:18 156:4 160:11, 13 173:6 174:4 191:20 196:3 197:18 204:15, 19 205:1, 3 210:6 211:24 212:19 213:22 216:8 221:1 222:6 233:18 236:14 239:1 253:6, 10 255:5 276:9 279:5 291:6 296:12, 24 309:1 310:14 324:10 343:18 350:15 359:1 371:13 379:13
believed 141:5
believes 25:23
belong 199:1
belongs 93:12
below, 240:21
beneficial 16:9
benefit 54:22 87:12 112:13 113:4
BENICAR 1:4 5:5 24:3 88:16 167:23 188:9, 9, 9, 11, 22 196:11, 23 198:4 216:12 320:22 326:2 332:1, 8 341:2, 20, 24 345:17 351:12, 18, 22
BENJAMIN 1:15 4:5, 14, 19, 23 5:8 9:4, 7 14:11 15:4 34:13 88:18 89:2 385:8
best 24:19 30:4, 11 32:2 33:6 37:19, 21 61:17 197:21 203:24 309:3
better 79:14 144:1 167:16, 22 171:3 175:18 185:23 186:21 187:5, 11 195:2, 8, 14 197:5 202:7 221:23 236:18 246:18, 23, 23 247:8, 10 248:5, 9, 10 285:8, 15 290:21 291:19 294:1 325:22 338:19 382:24
beyond 46:8 51:4 72:7 176:20 182:9 199:20 261:20 268:13 360:14
Bhagat 110:4
B-H-A-G-A-T 110:5
bias 149:7
BIDDLE 2:12, 17
big 95:5
biggest 277:2
bill 43:15
billed 40:19 41:8, 10
bills 85:18
binder 12:2, 5, 12 15:12 16:1, 2, 3 17:6, 11, 16 19:16

20:17 21:14 56:19 137:16
bioequivalence 258:15
biologic 51:6 67:23
biological 49:7 51:10 52:17 227:3 254:14 255:1, 11 256:10, 12
biologist 59:3
biology 72:8
biomedical 381:16
biopsied 121:22 122:17
biopsies 209:9, 10 210:7 257:11 377:2
biopsy 18:3 120:12 121:5, 16 122:19 123:12, 14 125:11 206:9 207:12 209:1, 20 210:5 273:3 278:10 318:7, 13 343:6, 8, 15, 17, 18, 22 344:1 375:24 376:14, 23
bit 36:21 112:20 127:7 211:4 212:10 244:18 263:7 359:13 367:23
black 280:7 344:4, 10, 17 353:17
blank 37:8
blinded 97:19 275:18
Block 39:11
blocker 258:5
blockers 6:8 54:1 96:16 109:3, 14 153:11 237:15 251:10 271:12
blockers, 53:10 110:3
blood 191:13, 17 285:11, 12
body 39:17 103:3
bone 169:9
Boolean 361:13
borne 120:8 122:7, 13 127:8 349:13
bottom 81:6, 24 148:12 150:11 165:5 177:15 213:11, 14 274:16 278:4 306:23 307:22 308:24 334:15 345:8, 9 373:21 377:16
boundaries 144:2
bouts 128:20
bowel 99:1, 5, 11 117:13 119:4 261:15 361:9, 10 363:1
box 320:23 326:3 330:22
Bradford 224:16, 18, 24 225:5, 9, 17, 21, 23 226:4, 6, 17, 19 227:1, 8 241:9, 12 254:11 378:5
branded 211:1
Braunstein 110:4 131:18 153:5, 9, 10 263:3 271:5
break 56:3, 5 140:1, 4 156:13 194:17 198:19 199:10 253:24 254:2 297:5 318:15, 18
breakdown 69:2
breeze 196:8
BRENNAN 2:17
brief 25:3 82:20 85:2 297:3, 5
bring 11:11, 20, 24 90:11 91:22
bringing 33:19
brings 9:18 24:8 27:6
British 361:21
broached 197:6
broad 52:17 55:17 117:22 144:9
broadly 53:23 55:14, 16
broke 141:1
brought 12:3 15:12 40:14 112:9 281:18
Budesonide 138:10 183:2 192:13, 14 195:15, 17, 18 244:1 245:19 246:2
bulk 63:8
Burbure 133:12 153:20

B-U-R-B-U-R-E 133:13

< C >
CACO 99:10 260:19, 21
Caco-2 260:21, 22 261:5, 7, 11 262:5
Cahill 1:17 10:14 385:13
calculated 158:16 258:19
call 119:15 189:11 193:4 285:16 318:16 327:24
called 35:8 47:12 78:20 91:11 95:7 100:10 295:14
Campus 2:18
cancer 26:21, 24 261:12, 20 264:4
cancer-derived 261:18
capacity 119:6 356:13 375:11
capital 115:1
Capsules 138:10
capture 150:19 264:12 360:4, 17 365:21
captured 228:14
care 27:1 171:5 202:24 205:10, 11 288:24
cared 178:17 298:14
career 236:7
careful 126:4 309:11
carefully 82:16 242:2
cares 291:15, 16, 16
caring 284:20
Cartee 5:12 135:11 140:14, 16 156:15, 16 179:2, 9 180:3 220:20 221:6
C-A-R-T-E-E 179:10
Cartee-Murray 179:9 184:3, 5
case 13:1, 2 23:10 25:19, 22 26:1, 19, 20 36:9 39:11 60:20 65:8, 21 74:18 75:11 77:18 79:2 94:22 100:23 101:16 107:7 110:9, 15, 16 112:13 122:5, 24 123:19 128:5, 7, 23 129:7 133:19, 20 141:10 142:5, 8, 12, 14, 15 144:5 147:12 148:11, 12 149:17, 18 150:10, 10 152:16, 21 171:17 176:16, 18 183:20 185:16 186:2 193:3 208:24 209:5 216:22 217:2 218:8 222:6, 7 229:11 232:5 239:23 240:20, 21 241:7, 18 242:2, 14, 15, 21, 21 243:7 247:11 248:11 251:6, 16 259:6 261:16 266:4, 5, 24 270:10, 12 278:5 279:21, 21 281:17 282:22 283:6 284:17 286:10, 13 287:21 288:12, 17 289:24 291:3 304:16 314:2 315:24 316:4 323:17, 18, 22 328:1 333:22 343:19 349:14, 14 353:16 373:8, 16, 21 378:9 379:7, 18
Case-Control 6:2 109:17

140:21 143:22 149:21 150:6, 18 151:3, 19 152:3, 7 153:1, 14, 16 154:19, 24 155:7, 22 156:3, 15, 18 239:3 262:20 266:7, 13, 21
cases 33:24 43:5, 23, 24 51:7, 9 72:12 137:11 143:17 169:18 171:1 172:17 195:8 206:4 220:9 222:10 230:12 264:21, 24 265:5 266:9, 23 289:2 305:15 316:22 338:6 345:3 353:20, 24 381:10
Caspard 81:16 86:6 353:21
cast 144:9 359:16 363:6 366:2 383:8
cataloged 355:21
cataloguing 356:3
catch 383:8
category 113:22 383:6
caught 289:17
causal 47:5 60:12, 21 68:13 92:1 216:24 315:19 317:5, 24 369:2, 12 370:12
causality 61:4 68:14 87:20 107:19 110:9, 17 111:14 114:6, 8, 12 146:10 147:14, 20 224:24 297:22 300:6 317:18 335:2, 4 336:24 370:7 371:8
Causation 4:24 23:18 28:5 34:14 107:19 112:22 115:8 130:10 132:21 133:7, 10 139:3 140:10, 11 142:24 163:16 316:12 317:11 372:4, 6
causation's 143:5
cause 23:19 62:1, 22 68:1, 11 69:12 71:19 74:15, 24 77:23 79:14 103:13 108:19 109:6 111:12 112:1, 5, 17 115:13 134:6 139:11 141:14 143:8 149:12 165:20 166:1 176:15 192:19 205:7 222:18 223:12 230:15 239:13, 14 251:14 257:15 304:2 316:6 318:4 323:5, 23 324:1 326:9 332:14 334:6 351:12
cause, 103:14
caused 23:24 166:10 201:8, 14, 18 251:20 252:5, 19 253:6 288:21 315:14
causes 48:13 53:20 57:21 59:14 61:22 63:3, 12 69:18, 20 77:8 78:22 103:9 107:24 108:8, 10, 15 109:18 111:22 115:1 131:6 133:24 135:24 146:7, 15, 19, 23 147:4 152:1 157:1 170:17 338:11
causing 65:12, 18 142:4 144:8, 17 166:22 216:12 222:8 332:24 334:21 337:14 351:19
caution 110:10 126:17
cautious 110:22, 23 111:18 162:8 250:18 276:6
caveat 110:19 134:14 202:22
caveats 363:4
Celiac 5:14 18:3 20:14 67:20, 22 68:4, 9 73:5, 10 74:1, 4, 8, 13, 16, 20 75:6, 9, 14, 18, 22 76:4, 10, 13 77:8, 20 78:3, 11, 16, 17, 20, 21 79:2, 11 93:20 116:5 120:18 121:1 122:14, 16, 21 123:4, 9, 15 125:10 164:10, 22 167:21 168:4, 5, 9, 12, 17, 19, 23 169:13, 15 170:3, 16 176:14, 17 177:8, 17 178:7, 9, 15, 19, 21 180:6, 20, 23 188:23 189:3, 5, 7, 14, 16, 20, 23 190:2 196:14, 16 200:22 204:4, 5, 10 210:12, 20, 21 211:7, 10, 12, 19, 21, 24 212:5 228:19 229:1, 3, 14 248:7 257:19 266:18 290:6, 11 291:3 296:17 343:19, 20, 21, 24 344:4, 7, 11, 14, 17 353:1, 4, 17, 20 354:1 356:6, 7 361:20, 22 365:12, 15 368:24 375:10
cell 99:1, 4 260:19 261:1
cells 99:10 260:20, 22 261:5, 7, 7, 16, 18 262:1, 5
cellular 51:4 52:14 55:14
center 250:16
certain 11:12, 20 20:15 43:24 45:7 65:15 67:20 80:15 95:19 99:1 163:14 164:6 178:13 180:5 212:16 216:1 217:5 232:15 241:6, 18 255:8 280:12 307:2 353:1 354:8, 14 357:8
certainly 20:11 25:5 29:19 30:16 40:16 49:5 50:1, 22 55:18 58:17 62:3 72:11 73:16 89:24 97:2 103:12 115:2 118:5, 24 121:12 122:3 123:3 125:9 134:20 156:22 164:5 166:3 170:24 177:1 179:20 185:13 188:24 204:18 223:14 244:4 279:20 289:9, 14 291:3 300:24 303:8 304:16 315:16 331:8 333:21 344:13 349:13 350:24 352:11 355:1 360:1 361:5, 6 362:14 365:6
certainty 47:8 166:14, 21 167:9 172:21 174:2, 22 211:15
CERTIFICATE 385:2
certification 385:17
CERTIFY 385:5
certifying 385:21
cervical 261:17, 20
cessation 193:1 246:24 254:22 378:19
cetera 91:19 146:16 281:13 282:7 375:3 377:23
chalk 98:11 125:23
chance 107:6 111:7 199:2
change 79:6 126:11 167:15

171:11 325:21 328:12 361:9, 10
changed 325:16
changes 49:7 50:7, 19, 21 51:10 53:23 54:2 117:12 288:20 290:23 296:6 329:13
characteristics 100:6, 16 277:9 333:11
characterizatio n 243:16
characterize 111:17 119:18 201:22 227:22 244:5 245:1 246:14 276:10 279:24
characterized 202:19 203:22 218:17 355:21
characterizes 244:15
characterizing 281:7 317:24
charged 82:13
chart 134:9 185:8 186:6 209:17, 19, 23
charts 184:22 188:8 196:1, 6 197:20 198:13, 24 203:1 349:1, 22
check 26:5 115:18 152:21 161:24 169:9 209:6 211:3 330:21 353:6
checked 115:6
checking 340:17
chemokines 51:4
Cherry 2:13
chest 101:9
child 168:20
choice 240:1, 10
chose 129:8 246:13, 16 265:4
Chronic 5:23 128:11, 19, 23 136:15 137:21 140:19 238:1, 7, 20, 23 239:11 262:17 383:12
chronology 203:5
CIOMS 7:5 346:3
circumscribed 317:1
circumspect 110:7, 19
circumstances 122:18 172:24 284:20 285:1
cite 21:3 146:6 149:16 177:10 200:12 227:7, 15 251:2, 5, 15 254:15, 19 255:15 256:12 278:10 334:24 335:22 336:4, 22 339:18 368:4
cited 94:12 154:12 163:11 217:23 305:17 368:2
Civil 1:4
Claiming 234:20
claims 229:15
claims-based 242:13
clarification 24:10 217:22 358:17
clarifications 327:15
clarifies 265:21
clarify 19:23 24:4 37:2 38:19 52:10 60:18 84:12 88:10 207:4 219:13 239:2
clarifying 207:7
classically 154:23
classification 116:10 266:2
classified 203:10 233:10
clear 17:7 32:18 51:21 52:6 53:16 85:17 90:9 130:1, 11 138:24 140:23 148:21 178:12 179:23 235:5, 8 244:13 261:24 277:15 286:4 303:13 308:20 355:3 370:5 371:23
clearly 43:10 68:10 169:6 176:16, 17 188:22 271:1 285:9 312:11 350:13
Clinic 140:22 180:6, 19 183:23 184:6, 14 185:17 186:13 231:23
clinical 16:24 50:3, 17, 20 53:11 57:22 58:11, 16 59:5 60:4 62:3 69:22 72:17 73:17 87:10 90:1 100:16, 20 101:12 111:3 116:23 117:10, 24 119:19 120:20 121:1 123:20 126:18 127:23 129:9, 18 136:16 141:16, 18 165:13 167:12 175:14 176:6, 9 177:20 183:3 187:1 205:21, 24 206:5 218:13 220:11 223:14 230:5 231:3 239:8 241:13 243:18 244:16, 24 246:21 250:12 252:21 253:8, 14 255:6 257:5 280:8 288:23 289:2 290:2, 12, 19, 20, 24 291:17 293:10 296:21 298:11, 13, 15 305:9, 10 306:5 323:10 325:7 333:12, 16 349:19 352:18 354:19 360:19 377:6 382:13
clinically 78:6 202:4 206:19 245:18 280:10 291:9, 20 293:13
clinicians 20:21
clinician's 211:11
clinicopathologi c 58:9
Clinic's 145:5
close 305:15 308:14 338:17
closed 46:2
closely 75:23 82:16 211:4 232:18
code 116:11
coded 326:3
codes 116:2 357:15, 18
Coeliac 361:15
cofactor 67:6, 12 69:7 72:6
cofactors 69:14, 15
coherence 226:11, 16, 21
coherent 229:12 250:3
cohort 149:21 150:5, 18 151:2, 12, 18 152:19 154:7 155:8 227:21, 23 242:24 266:13, 14
colitis 362:19 364:15, 19, 20
collaborate 164:14
collaborated 164:11
collaboration 151:6
collaborations 164:23
Collagenous 97:17 129:13 364:20, 22
collated 304:19
colleague 93:23
colleagues 56:16 65:22 66:1 75:17 93:19 94:8, 22 97:16 98:4, 18 109:12 112:14 113:2 114:14 115:16 128:13 133:5, 12 135:13, 18 136:14, 20 137:10, 20 138:1, 9 140:18 144:4 145:4 146:3 155:3, 24 184:22 187:23

196:8, 22 198:3 202:7 204:7 232:2 248:2 268:8 273:1 287:4 368:13, 20
collected 200:5 204:11
collection 60:22
colloquially 59:7 101:8
colon 26:21, 23 261:12 264:3
colonic 261:11 262:1
colonoscopies 26:22
colonoscopy 157:17 263:15, 21, 24 264:2, 4, 22 265:3, 8
Columbia 235:23 236:7 292:16
column 206:15 213:8, 12 277:3 375:24 376:8, 13, 14 377:16
columns 157:13 206:14, 16, 17
combination 191:20 338:5 361:12
come 20:23 42:5 53:14 75:12 79:12 91:23 93:9 141:21, 23 171:7 183:22 185:18 204:10 239:19 240:10 299:21 306:11 339:3 366:7, 19
comes 142:10 145:17 190:19 191:20 293:17
coming 186:12 251:7 332:23 350:11 379:19
comment 78:13 94:14 207:10 329:23
commentary 103:18 368:12
commented 229:22
commenting 154:6
common 116:22 117:1, 2 118:3, 4, 17 119:22 120:1 121:19 124:3, 18 128:1 141:3, 4 145:9, 23 159:6 162:4 185:1 210:21 239:13, 18 241:16 263:13 265:15 267:6, 8 274:4 279:6 280:16 312:23 322:16, 23 324:15, 18 325:2 327:23
commonly 118:1 127:3 192:13 280:13 317:17 363:19
communicated 27:13
communication 12:16 229:8
communications 32:14 45:6 163:2 298:19
community 64:24 113:17 121:9 177:23 374:20 380:1, 11 381:7, 16
companies 380:2
company 82:4 298:1, 20 299:10, 16 301:2, 9 307:2 316:13 379:23 380:7
comparative 97:18
compare 222:2 248:15 273:5 277:10
compared 6:7 53:9 70:3 110:2 159:12 192:16 212:7 237:14 248:1 257:6 258:3 263:15 271:11 273:1, 6
comparing 71:13 276:7
comparison 260:1
comparisons 258:7, 9, 11
compatible 121:12 289:9, 12 350:24
compelling 103:24 166:5 285:19
complained 141:12
complaints 347:22 348:2
complement 212:3
complemented 87:8
complete 35:15 37:12 137:15
completed 37:20 94:24 303:7
completely 372:11
completeness 177:21
completion 385:8
complication 114:21
complies 216:17
component 166:7 224:17
components 69:4
comprised 40:5
computer 37:8 357:4
conceived 203:7
concentration 258:17 260:4, 7
concentrations 259:4, 21, 24 260:12
concern 344:20
concerned 230:4 304:3
concerning 229:7
conclude 107:23 111:24 139:1 144:18 151:24 196:12
concluded 79:1, 4 101:23 141:13 142:3 196:15 201:16, 20 203:12 273:20 384:5
concludes 111:21
concluding 146:6 317:4
conclusion 22:15 47:3 60:8 87:14, 19 89:15, 16, 18 103:4, 8 108:20 111:9 112:3, 12 113:15 114:7 129:4 131:5 135:23 138:23 139:11 140:11 144:21, 22, 22 146:13, 18 156:23 185:11 186:8 267:11, 13 332:24 379:3
conclusions 146:1
concomitant 313:2 343:20
concrete 43:7 48:6 190:11
condition 48:13 87:11 100:4 117:4 119:21 165:11, 12 169:17 177:5, 16 183:19 186:14, 15, 16 201:18 202:16 240:17 245:1 251:20 252:8 253:1 354:1 355:20 361:17 365:1 381:8 383:1
conditions 55:23 177:3 211:9 306:7 361:16
conduct 58:23 286:2
conducted 50:9, 12, 22 51:13, 22 52:24 53:19 235:23 333:4 334:1
conferences 58:9
confidence 158:5, 14, 17 159:1, 7, 8
confident 24:22 96:1 212:4 270:12
confidential 299:9
confirm 308:2 346:17 348:15 378:1
confirmed 186:18
confirming 25:4

confused 336:*17*
confusion 215:*18*
congruence 328:*16*
congruent 87:*2*
connection 246:*5* 256:*9*
consequence 158:*23*
conservative 111:*18*
consider 30:*24* 111:*11* 118:*24* 119:*13* 123:*23* 294:*20* 351:*7* 358:*11* 361:*19, 22, 23* 362:*1, 6, 9* 363:*22* 364:*21* 365:*10, 17* 378:*6, 14*
considerable 278:*6*
consideration 225:*5*
considered 128:*10* 194:*5, 7* 247:*14* 281:*11* 334:*9* 378:*10*
consistency 240:*19* 241:*9, 12, 18*
consistent 369:*4*
consistently 356:*4, 12*
constipation 127:*12, 18* 128:*3, 6, 20* 278:*8, 15, 20, 24* 279:*7, 7, 9* 324:*18*
constitute 36:*9*
constitutes 17:*11* 90:*16*
constrained 270:*20*
consult 163:*19*
consultation 14:*2*
consulting 39:*10*
Contact 6:*22* 340:*1*
contacted 30:*8* 188:*13* 190:*9* 196:*17*
contemplating 57:*20*
contend 31:*20* 336:*23*
Contents 56:*21, 23* 80:*5* 105:*9* 305:*4*
context 262:*7* 290:*10* 301:*12, 19, 22* 302:*3, 14, 21* 304:*18* 305:*23* 306:*3* 338:*19* 345:*1* 364:*24* 370:*10* 372:*21*
contexts 373:*10*
continue 130:*1* 365:*3*
continued 326:*2, 24* 332:*8*
continuous 294:*15*
contrary 61:*1* 108:*14*
contrast 176:*9*
control 152:*16, 21* 154:*22* 183:*4* 239:*24* 265:*15* 266:*4* 273:*3, 15* 275:*7, 9* 276:*22* 277:*11* 385:*20*
controlled 63:*16, 19* 148:*10, 23* 150:*22* 151:*14* 256:*19, 21* 260:*13* 284:*19, 24* 285:*17*
controls 155:*6* 263:*16* 264:*21* 265:*6, 19* 267:*1* 273:*7, 12, 24* 274:*20, 24* 275:*12, 22* 276:*12, 17* 277:*6*
controls, 274:*5*
controversy 368:*21*
conversation 24:*24* 27:*21* 187:*7* 195:*20* 215:*2, 23*
conversations 32:*20* 33:*14* 36:*24*
convey 130:*24*
convincing 60:*20* 61:*24* 62:*15* 110:*8* 123:*19* 168:*2* 197:*3* 242:*17* 373:*16*
copy 12:*13* 105:*8* 179:*8*
Correct 12:*22* 15:*16, 17* 26:*18* 29:*6, 7, 9, 10, 15* 31:*8* 32:*6* 39:*3, 5* 40:*5, 6, 9, 10* 42:*3, 4* 47:*10, 11* 53:*21* 57:*15* 58:*4* 61:*16, 18* 65:*10, 18* 80:*16, 17* 81:*17, 21* 82:*1, 2* 83:*8* 84:*5, 21, 22* 85:*6, 10, 21* 86:*1, 2, 4, 7* 89:*13* 90:*20* 91:*15* 92:*12* 95:*23* 100:*14* 101:*4* 115:*23* 118:*19* 131:*17* 137:*5* 146:*8, 9* 147:*17* 149:*22* 159:*16, 21* 160:*23* 162:*17* 164:*1* 169:*21* 171:*14, 24* 174:*10* 178:*7, 15* 179:*19* 183:*12* 185:*12* 186:*9* 193:*8* 195:*4* 197:*20* 200:*13, 14* 205:*8, 18, 23* 206:*11* 209:*22* 210:*13* 211:*9* 213:*19* 214:*11* 215:*21* 217:*9* 221:*9* 224:*16* 225:*1* 227:*9* 228:*19* 231:*7* 232:*12* 233:*14* 236:*1* 241:*20* 243:*10, 14* 244:*7* 247:*4* 249:*7* 251:*4, 21* 252:*19* 254:*18* 256:*10* 258:*4, 9* 261:*3, 9* 263:*4, 5* 267:*12, 21* 271:*21* 272:*22* 274:*6, 13, 22* 275:*15* 276:*3, 15, 16, 23* 277:*18* 278:*11, 16, 17* 279:*11* 292:*13* 294:*8* 295:*9, 15* 297:*24* 300:*18* 308:*6, 8* 309:*7* 313:*14* 314:*7* 316:*7, 9* 319:*13* 321:*21* 322:*2* 323:*24* 324:*8* 328:*5, 8* 329:*16, 19* 331:*5* 332:*20* 337:*1, 20* 340:*16* 341:*3, 20* 342:*2* 347:*1, 19, 23* 348:*2* 355:*5, 19* 376:*5* 378:*4, 16* 379:*21*
correctly 10:*22* 348:*14* 349:*8*
correlate 232:*17* 291:*1* 296:*20*
correlated 159:*4*
correlates 229:*10* 340:*18*
correlation 115:*8* 156:*20* 229:*4*
correspond 164:*13, 20*
corresponds 308:*2*
corticosteroid 183:*3*
corticosteroids 247:*9*
cost 41:*24*
Counsel 3:*2* 11:*5* 12:*17* 13:*10* 14:*2, 19, 23* 24:*3* 32:*21* 46:*21* 198:*10* 300:*18* 370:*8* 377:*10*
count 191:*24* 236:*14* 270:*16, 23*
country 189:*21* 264:*6*
couple 9:*21* 30:*6* 104:*6* 114:*18* 140:*8, 23* 141:*2* 307:*4* 309:*16* 363:*13* 366:*18* 369:*18*
course 17:*3, 5, 5* 27:*22* 64:*2, 13, 14, 21* 65:*5, 7, 9, 13, 15* 70:*12* 90:*2* 95:*11* 99:*14* 112:*12* 142:*6* 165:*13* 175:*16,*

20 194:12 226:4 261:18 285:4 290:16 300:11 302:12 325:16 329:20 377:9 378:18
COURT 1:1 48:22 55:8 66:14 70:17 173:12 249:20 312:7
covered 156:8
cradle 151:9
Crawford 81:20
crazy 363:5
created 301:13, 16, 17
creation 302:4
criteria 77:19, 22 78:4 128:9 184:12 224:18, 24 225:9, 21 226:5, 6, 10, 17, 20 227:1 241:12 246:9, 11 247:16 248:14 253:18 254:11, 21 257:14 313:23 333:16 378:6, 7, 10, 15, 18, 20
criterion 78:5 183:16 225:12, 14, 16, 22 226:11 227:9 240:18 241:9, 20 245:14 250:23 251:4 254:14 255:1 256:23 348:16
criticism 151:1
cropped 186:2
cross-sectional 97:18
cry 325:6
crypt 123:24
CSPV 334:18
CSPV's 335:3
culprit 145:10
190:21 201:21
cultures 59:9
cumulative 67:4 221:22
curious 13:22
current 25:7 239:7
curse 95:7 99:12
cut 208:7, 16
cutaneous 138:2
cutoff 160:5 175:20
cytokines 51:3

< D >

Daiichi 2:15, 20 3:3 9:17 82:3 136:7 297:18 300:21 323:17 345:15 353:3 356:2 380:19 382:8
Daiichi-Sankyo 319:7 339:16 340:22
daily 294:19 295:1 322:12
damage 67:4 304:3
Daniel 102:6
dark 351:21
data 60:4, 6, 23 61:1 113:5 115:24 145:19 151:21 167:5 173:22 174:24 203:5 205:17 209:18 210:5 218:12 221:22 228:3, 5, 7, 15 229:16 230:24 231:1, 5 232:12, 14 233:9, 10, 12 239:21 240:2, 15 242:13, 20 246:21 247:21 254:24 282:18 291:5 293:17 296:22 316:18, 21, 23 317:1, 1, 15 324:11 325:23 329:10 369:20, 22 373:18 377:13, 19 378:2 383:22
database 120:20, 22 354:3, 5, 7, 13, 17 355:4, 8, 14, 18 356:16 357:9 358:8 368:19
date 1:17 28:1, 21 29:8 37:18, 20 53:4, 12 84:6 97:23 196:3 202:11 302:16 309:23 310:1, 4 330:19 351:16 369:21
dated 39:3 42:16, 16, 18 85:6 385:15
dates 29:5 40:7 381:4, 5
daunting 37:7
day 16:11 32:19 37:15, 16 59:10, 10 102:4 157:22 176:6, 8 198:1 240:3 253:11 294:24 311:4 365:18
days 116:14 170:1 251:23 252:18 293:16, 19, 22 331:23 350:18
day's 39:20
day-to-day 58:11 298:10 305:10
de 133:19 154:13
deafening 251:18
deal 238:3
dealing 217:23
deals 232:11
dealt 303:21
death 173:4
decades 151:13
December 23:6
deceptive 233:19
dechallenge 142:16 165:15 166:9, 15 167:1, 5, 11, 13, 20 168:2 172:1, 12, 19 173:17, 21 174:10, 17, 24 175:2, 10, 17 203:5 217:2 242:19 254:24 283:15 288:5 289:10 295:11 319:17 326:11 329:9 373:9, 17
dechallenged 200:3 291:10
dechallenges 293:22 345:2
decided 77:5
decisions 298:4
deck 248:17
declared 117:16
decreased 383:13
deemed 218:22 230:14
deep 59:22
deeply 59:16 88:9
Defecation 362:5, 6
defendant 23:13, 15
Defendants 4:17 9:18 14:10 15:3 61:9, 14
deficiencies 117:17
deficiency 119:9 121:3
define 175:6, 9 316:3
defined 117:8, 22 124:21 126:5 128:8 168:13 221:23 278:6
definite 315:21 318:2
definitely 303:22
definition 227:24 246:16 247:8 250:5 266:8 295:10, 21 298:7
definitions 101:15 125:4 127:6 333:14
definitive 167:4, 17 173:21 174:9, 12, 14, 16, 17 175:2 203:4
definitively 152:20 166:1, 9 172:9 240:13
DeGaetani 5:17 56:15 57:6 132:16 153:15 200:12, 17, 24 204:1 205:13 218:4, 6, 12 243:11 248:13 375:16
degree 47:8 83:20 143:16 166:13, 21 167:8 172:20 174:1, 21 206:5 239:6 242:18 244:13 245:3 331:11
degrees 93:21 122:8

dehydration 51:*8* 284:*7* 319:*12* 320:*22* 332:*3* 334:*22* 337:*15* 347:*23* 350:*20*, *24* 365:*23*
deliberate 283:*15*, *20*
deliberately 286:*5*
demarcated 43:*10*
demise 166:*24* 173:*16*
demonstrate 335:*2* 371:*24*
demonstrated 274:*11* 276:*14* 277:*17*
denied 61:*12*
denominator 246:*8*
denoted 218:*15* 220:*7*
density 169:*9*
deny 62:*16*
denying 235:*6* 337:*13*, *17*
dep 198:*15*
department 58:*24*
depend 36:*20* 151:*4*
depending 118:*23* 245:*22* 266:*19*
depends 96:*9* 143:*12*, *12* 244:*18* 359:*13*
deposed 23:*4* 26:*8* 82:*4*
deposition 1:*7* 4:*14*, *20* 6:*18* 8:*2* 9:*2*, *3* 11:*3*, *4* 14:*8*, *13*, *18* 15:*5* 23:*1*, *3* 25:*1* 26:*9* 28:*9*, *17* 34:*11*, *20* 35:*22* 38:*1* 41:*12* 77:*14* 80:*15* 81:*20* 82:*1* 84:*4*, *11*, *20* 85:*9*, *21* 88:*14* 89:*1* 91:*14* 96:*24* 101:*22* 102:*3*, *5*, *16*, *18*, *20*, *21* 178:*23* 179:*8* 200:*20* 255:*22* 262:*14* 263:*1*, *9* 271:*7* 307:*8* 308:*6*, *12*, *14* 320:*2*, *12* 335:*1*, *10*, *12*, *19*, *20*, *21* 336:*18*, *23* 339:*23* 345:*24* 357:*24* 367:*8* 380:*20* 383:*3* 384:*5* 385:*6*, *8*, *9*
depositions 61:*10* 82:*11*, *12*, *15* 83:*10*, *14* 85:*3*, *12* 89:*11* 90:*18* 94:*5* 100:*3* 300:*12* 301:*10* 302:*13*, *14*
deps@golkow.com 1:*23*
depth 83:*12*, *17*, *19* 88:*11* 123:*24*
derivation 261:*12*
derive 242:*12*
derived 261:*11*
describe 25:*24* 129:*9* 283:*13* 286:*11*, *14*
described 55:*19* 133:*19* 188:*14* 211:*6* 217:*2* 247:*20* 282:*16*, *24* 283:*7* 296:*23* 334:*23* 337:*16*
describing 184:*10* 263:*11* 278:*7*
DESCRIPTION 4:*12* 29:*5* 129:*19* 211:*5* 239:*7* 281:*17* 320:*19*
design 144:*19* 145:*18* 202:*23* 266:*19*
designed 63:*20* 157:*21* 231:*11* 233:*23* 239:*3* 247:*18*
designer 56:*14*
designing 63:*23*
designs 239:*20*
desk 316:*19* 325:*3*
desperate 197:*1*
despite 323:*13* 342:*4* 373:*19*
detail 93:*11*
details 25:*20* 338:*7*
detect 233:*24* 270:*8*
detected 158:*19* 270:*3*
determination 324:*9* 338:*11* 372:*5*
determine 17:*9* 33:*1* 205:*7* 263:*12* 281:*23* 292:*1* 316:*6*
determined 143:*7* 202:*12* 214:*2*
develop 67:*22* 69:*8*, *15* 76:*5*
developed 96:*20* 97:*3* 253:*18* 340:*24*
developing 68:*19* 97:*5* 342:*15*
development 72:*5* 150:*20* 280:*21*
develops 70:*4* 76:*9*
diabetes 364:*2*
Diabetic 363:*21*
diabetics 363:*24*
diagnose 118:*21* 120:*3* 126:*23* 290:*9* 306:*6*
diagnosed 73:*20* 74:*20* 117:*3* 119:*23* 165:*12* 168:*17*, *19* 169:*13* 184:*14* 196:*14* 248:*6* 343:*22*
diagnoses 211:*1* 229:*15*
diagnosing 306:*9* 380:*12*
diagnosis 26:*24* 50:*17* 64:*22* 72:*19* 73:*8* 78:*22* 100:*17* 120:*18* 124:*4* 168:*14* 172:*21* 180:*16* 189:*4*, *6* 210:*12* 212:*20*, *21* 214:*11*, *13* 228:*13* 306:*13* 315:*13* 316:*9*, *11*, *15*, *17* 317:*3*, *13*, *16* 318:*3* 332:*23* 333:*4*, *13*, *21* 334:*2*, *4* 343:*24* 350:*21* 353:*18* 357:*15*, *18*
Diagnostic 5:*15* 57:*3* 78:*1* 200:*23* 257:*17* 381:*23*
diagrams 212:*13*
Diarrhea 5:*24* 51:*8* 119:*1*, *15* 120:*11* 121:*2* 126:*21*, *22* 127:*2*, *6*, *9* 128:*1*, *11*, *19*, *24* 137:*21* 140:*20* 143:*22* 144:*8*, *11*, *17* 145:*9* 157:*5* 159:*10* 160:*3* 183:*4* 238:*1*, *8*, *16*, *17*, *20*, *23* 239:*11* 262:*18* 263:*14* 264:*8*, *20* 265:*1*, *2*, *4*, *10*, *16* 266:*10*, *17*, *24* 267:*19*, *23* 268:*23* 278:*9*, *16*, *19* 279:*6*, *10*, *14* 280:*14* 312:*15*, *24* 313:*10*, *11* 314:*6*, *13*, *18* 315:*9* 319:*12* 320:*21* 325:*5* 326:*1*, *3* 330:*13* 332:*3*, *7* 334:*22* 337:*15* 341:*1*, *19* 348:*2*, *7*, *12*, *13*, *15*, *18*, *23* 349:*3*, *5*, *12*, *17* 350:*3*, *7*, *12* 351:*22* 362:*8* 365:*5* 383:*12*
Diarrhea, 136:*15*
diarrheal 111:*10* 288:*21* 296:*6*
dictated 246:*11*
dies 166:*18*
diet 78:*15* 168:*21* 180:*22* 197:*7*, *15* 211:*14* 212:*7* 281:*2*, *5*, *10*, *15* 290:*10* 342:*11*

dieting 342:*1, 4, 6, 9*
differ 277:*8*
difference 247:*2, 5* 266:*12* 291:*8*
differences 72:*2, 9* 259:*1* 273:*22* 276:*9*
different 27:*15* 69:*19* 73:*22* 100:*19* 117:*9, 9* 125:*12* 126:*1* 144:*14* 170:*8* 171:*14* 246:*7, 8* 247:*3* 248:*1, 14* 249:*6* 251:*13* 253:*13* 257:*4* 258:*6* 333:*16* 353:*11* 359:*23* 361:*8, 16* 362:*3* 363:*13* 367:*13* 372:*12, 19* 378:*7*
differential 306:*13* 316:*8, 10, 15, 17* 317:*3, 13, 16* 318:*3* 332:*23* 333:*4, 12, 18, 20* 334:*1, 4* 351:*5*
differently 37:*5* 125:*12* 245:*3* 362:*7*
difficult 10:*14* 189:*24* 197:*15* 298:*17*
Dilemma 5:*16* 57:*4* 200:*24*
diminish 149:*7, 17*
dimly 95:*16*
dinner 235:*17*
dire 195:*19*
direct 79:*16* 129:*20* 147:*7* 158:*23* 177:*11* 205:*12* 212:*24* 219:*17* 224:*20* 235:*8* 274:*9* 297:*9* 334:*10* 335:*6* 385:*20*
directing 319:*1*
Direction 8:*5*
directly 19:*17, 22* 20:*7, 8* 45:*8* 234:*14* 276:*7* 306:*19*
disagree 243:*23* 316:*16*
discharge 284:*8*
disclosed 13:*3*
discontinuation 78:*6* 183:*17* 195:*3* 202:*8* 246:*2* 281:*22* 282:*1, 14* 287:*12, 17, 19* 295:*22* 326:*17* 369:*6* 377:*18*
discontinue 168:*11* 191:*12* 192:*8* 201:*24*
discontinued 186:*22* 187:*6* 206:*11* 215:*5* 216:*3* 217:*9, 18* 218:*10* 282:*6* 295:*8* 326:*19, 22* 328:*5, 8* 331:*12* 332:*2*
discontinuing 209:*2, 22*
discovered 201:*13* 203:*11* 246:*5*
discovering 196:*10*
discrete 175:*21*
discuss 243:*8* 261:*1* 286:*19* 295:*7* 340:*14* 371:*5*
discussed 26:*11* 96:*23* 163:*7* 184:*2* 219:*2, 8* 220:*21, 23* 233:*11* 240:*22* 272:*24* 278:*5* 280:*24* 298:*13* 305:*21* 363:*4* 368:*14*
discusses 299:*7* 319:*11*
discussing 43:*23* 50:*15* 68:*14* 198:*2* 220:*19* 292:*23*
discussion 22:*6* 43:*5* 87:*7* 94:*4* 207:*24* 213:*3, 7* 284:*16* 307:*19* 377:*15, 15*
discussions 380:*22*
disease 18:*3* 20:*14* 67:*20, 22* 68:*4, 10* 73:*6, 11* 74:*1, 4, 9, 14, 16, 21* 75:*6, 9, 15, 18, 22* 76:*5, 10, 13* 77:*8* 78:*4, 11, 17, 17, 21* 79:*2, 11* 93:*20* 99:*1, 5, 11* 116:*6* 120:*19* 121:*2, 21* 122:*14, 16, 22* 123:*4, 9, 16* 125:*10* 164:*10, 22* 167:*21* 168:*4, 5, 9, 12, 18, 19, 23* 169:*13, 16* 170:*3, 16* 176:*15, 17* 177:*8, 18* 178:*7, 9, 15, 19, 21* 180:*6, 20, 23* 188:*23* 189:*3, 5, 7, 14, 16, 20, 23* 190:*2* 196:*14, 17* 203:*13* 204:*4, 5, 10* 210:*12, 20, 21* 211:*8, 10, 12, 20, 22* 212:*1, 5* 228:*19* 229:*1, 3, 14* 245:*5* 248:*7* 257:*19* 266:*18* 290:*7, 11* 291:*3* 296:*18* 342:*11* 343:*19, 21, 21, 24* 344:*4, 7, 11, 14, 18* 353:*1, 4, 18* 354:*1, 5* 356:*6, 7, 10* 361:*15* 365:*12, 15* 368:*24* 375:*10*
diseases 111:*4* 116:*11* 261:*22* 262:*7* 343:*20*
dismiss 285:*18*
disorders 75:*2, 5* 78:*2* 79:*10* 177:*19* 257:*18*
disparaging 284:*15*
disparities 18:*2* 120:*18*
dispute 61:*4* 99:*9* 181:*6, 7*
disrespect 164:*12* 193:*12*
disseminated 230:*19* 352:*11*
dissemination 310:*6, 7*
dissolving 259:*18*
distinct 211:*9*
distortion 122:*9*
distressing 350:*11*
distributed 250:*15*
DISTRICT 1:*1, 2*
disturbances 325:*19*
diversion 149:*19*
divulging 25:*21*
Doctor 14:*17* 34:*18* 35:*6* 38:*8* 45:*11, 11* 64:*12* 69:*17* 72:*13, 13* 88:*23* 106:*12* 125:*18, 22* 177:*5* 179:*6, 15* 199:*17* 205:*13* 207:*1* 208:*19* 217:*15* 221:*16* 230:*23* 235:*22* 252:*15* 254:*9* 256:*6* 262:*24* 268:*7* 282:*23* 288:*18* 297:*9* 298:*18* 299:*16* 304:*13* 306:*20* 307:*16* 308:*20* 310:*9* 317:*9* 319:*1* 320:*10* 321:*21* 335:*17* 340:*12* 345:*5* 366:*14* 367:*2*
doctors 73:*14* 188:*4* 243:*23* 380:*8* 382:*12*
doctor's 13:*23*
Document 5:*5* 13:*7* 14:*18* 15:*7, 10* 29:*4* 80:*23* 85:*8* 88:*15* 89:*3* 233:*1, 3, 6, 7* 300:*9* 301:*15, 16* 302:*2, 4, 16* 310:*18* 311:*16* 312:*19* 320:*13* 321:*13, 19* 328:*3, 3, 10* 330:*5, 10* 331:*10* 343:*13*
documented 78:*19* 312:*12* 313:*8*
documenting 345:*14*

Documents 8:*9* 11:*12, 20* 12:*7* 16:*15* 84:*24* 91:*18* 95:*17* 136:*7* 297:*13, 19* 298:*2, 6* 299:*8, 9, 11, 18, 21* 300:*3, 13, 15, 22* 301:*9, 13, 23* 302:*11* 340:*23* 374:*19* 379:*23* 380:*19*
dogmatic 175:*19*
doing 24:*2* 39:*7* 98:*15* 139:*4, 5* 189:*10* 207:*7* 253:*21* 291:*9, 10, 21* 297:*2* 333:*18* 366:*10*
domain 50:*23* 57:*23*
Donald 80:*22*
dosage 223:*23* 224:*2* 258:*13*
dosages 223:*3*
dose 221:*20, 22* 222:*14, 18, 20* 223:*18* 224:*8* 329:*12*
dose-response 222:*4* 223:*21, 24* 224:*12, 15, 17*
doses 175:*21, 24* 221:*17* 224:*10* 293:*19*
dosing 223:*4* 224:*12, 13*
double-check 96:*4* 212:*22*
doubt 329:*5*
DQ8 211:*18*
Dr 5:*8* 9:*14* 13:*2* 22:*19* 28:*15* 48:*10* 53:*2, 17* 59:*12* 61:*19* 85:*20, 24* 86:*19* 87:*3, 12, 17, 17, 22* 88:*5, 18* 89:*2, 12* 93:*23* 102:*5, 15, 17, 20, 21* 103:*8, 18, 23* 128:*12* 164:*5, 9, 16, 24* 184:*21* 185:*15* 187:*7, 22* 198:*23* 200:*2* 202:*13, 15* 204:*1, 2* 214:*15, 19, 19* 215:*3, 13, 20, 20, 24* 216:*1* 263:*3, 3* 271:*4, 5, 20* 324:*5, 6* 332:*18* 333:*2, 24* 349:*2, 23* 358:*6*
dramatic 187:*1* 197:*3* 289:*3*
draw 47:*1* 145:*24*
drawer 240:*2*
drawn-out 285:*5*
DRINKER 2:*12, 17*
drip 294:*15*
Drive 2:*18*
Drs 12:*14*
drug 12:*15* 23:*18, 24* 78:*6* 163:*1* 182:*20, 21* 221:*8, 14* 229:*8* 260:*4* 284:*16* 288:*5, 7, 8, 10, 13, 19* 292:*11, 12, 15, 23, 24* 293:*9, 24* 294:*7, 18, 24* 295:*15* 301:*3* 304:*8, 11, 17* 315:*20* 318:*1* 325:*1* 330:*7, 24* 331:*4, 11, 15, 22* 332:*11* 338:*5* 352:*4* 367:*5* 369:*6*
Drug-induced 135:*12* 136:*15* 137:*20* 154:*18* 247:*22*
drug-related 306:*11*
drugs 251:*21* 252:*6* 260:*7* 294:*14, 16* 306:*4* 323:*1* 338:*4, 5* 359:*5*
due 37:*16* 50:*4* 71:*4* 73:*9* 109:*1, 4* 111:*6* 119:*5* 122:*17, 20* 177:*19* 195:*9* 228:*23* 247:*23* 252:*23* 283:*16* 285:*9* 364:*2*
duly 385:*5*
duodenal 18:*2* 120:*12* 273:*3* 278:*10*
Duodenitis 96:*18*
Duodenitis, 153:*13*
duplicate 346:*16*
duplicates 346:*20*
durability 250:*9*
durable 245:*24*
duration 66:*2* 73:*7* 151:*5* 221:*23* 287:*11, 17, 22* 288:*4, 10* 293:*4, 5* 295:*13, 17, 20* 330:*24* 331:*4* 332:*11* 367:*18*
durations 295:*18*

< E >
earlier 24:*16* 28:*19* 52:*7* 89:*23* 102:*24* 129:*11* 137:*2* 141:*1* 173:*3, 4* 178:*11* 179:*11* 203:*16* 219:*8* 239:*2* 250:*7* 253:*10* 260:*18* 263:*7* 278:*21* 294:*13* 296:*23* 313:*24* 367:*7* 368:*14* 371:*12* 373:*14* 383:*23*
earliest 313:*21*
early 30:*5, 8* 32:*3* 34:*6* 72:*4* 153:*23* 178:*9* 214:*20* 239:*4* 359:*17*
easier 105:*16, 24*
easy 16:*9* 104:*5* 304:*9, 12*
eat 272:*16*
eating 189:*9* 197:*16* 290:*8*
editor 231:*24*
editorial 62:*18* 108:*24* 152:*15*
effect 66:*23* 67:*4* 169:*5* 239:*17* 268:*5* 284:*17* 303:*4* 306:*11* 325:*18* 374:*4, 7*
effective 175:*9*
effects 58:*18* 151:*20* 176:*20* 192:*15, 16* 233:*4* 304:*8, 11* 306:*4* 322:*16* 323:*1* 324:*15, 15, 19* 325:*2* 373:*24*
efficacy 148:*15*
effort 205:*6*
efforts 382:*24*
EGD 157:*15* 263:*15, 20, 24* 264:*22* 265:*2, 14, 16*
EGDs 264:*5*
Eisenhower 2:*3*
either 30:*14* 35:*11, 13* 67:*3* 85:*12* 100:*3* 113:*12* 130:*2* 132:*21* 137:*6* 138:*24* 139:*1* 145:*23* 154:*15* 170:*15* 184:*11* 187:*11* 192:*11, 24* 195:*16* 196:*6* 209:*10* 218:*20* 230:*13* 237:*23* 238:*3* 239:*23* 243:*5* 245:*1* 246:*22* 251:*24*
elected 281:*11*
electronic 196:*6*
elements 306:*17*
elevated 290:*11*
elicit 352:*16*
E-Mail 7:*3* 311:*24* 318:*16* 346:*1*
e-mails 30:*13*
embarking 293:*1*
emerging 230:*1* 244:*24*
emphasize 150:*13*
employ 355:*3*
employed 299:*15* 317:*17* 355:*1*
employees 298:*20*
employing 355:*7*
encapsulations 306:*2*
encounter 69:*4* 111:*10* 171:*17*

encountered 108:*11* 300:*10*
encountering 128:*14* 244:*24*
encouragement 197:*13*
endeavor 316:*5*
ended 142:*19* 189:*6* 196:*16* 197:*16*
endoscope 239:*11*
Endoscopic 6:*1* 140:*21* 262:*19*
Endoscopy 18:*5* 120:*16*, *20*, *22*, *24* 121:*4*, *14*, *15* 122:*1* 123:*6* 239:*19* 264:*11*, *14* 265:*12* 267:*24* 269:*20*
endoscopy, 267:*20*
endpoints 356:*9*
ends 114:*14*
engage 43:*5*, *13* 316:*8*, *10*
engaged 23:*12*, *14* 27:*8* 33:*3* 61:*15* 302:*23*
engagement 31:*17*
engine 98:*11*
ensuing 186:*3*
ensure 259:*24*
entails 175:*10*
enter 355:*7*
enteric 127:*16*
Enteritis 362:*10*, *12*
Enterocolitis 362:*15*
enterocyte 259:*15* 260:*5*
Enteropathy 5:*11*, *20* 20:*16*, *22* 31:*1* 33:*9*, *12* 34:*1* 47:*7* 48:*14* 49:*9* 50:*17* 53:*21* 54:*7* 55:*22* 61:*13*, *22* 62:*2*, *2*, *5*, *9*, *13*, *17*, *23* 63:*3*, *9*, *13*, *21* 64:*4*, *7* 65:*1*, *12*, *18* 67:*14* 68:*19* 69:*9*, *12*, *18*, *21* 70:*2*, *4* 71:*1*, *8*, *15*, *20* 72:*18* 73:*12* 74:*2*, *7*, *9*, *12*, *24* 76:*6*, *8* 77:*24* 87:*5* 100:*5*, *7*, *8*, *9*, *10*, *11*, *12*, *13*, *24* 101:*17* 103:*9* 107:*24* 108:*9*, *10*, *16* 109:*1*, *18* 110:*11* 111:*5*, *22* 112:*2* 113:*12* 115:*2* 116:*9*, *12*, *20*, *21* 117:*7* 118:*22* 119:*2*, *23* 120:*5*, *10* 121:*13*, *20* 122:*24* 123:*21* 124:*4*, *20* 126:*24* 127:*4*, *10* 128:*2*, *15* 131:*6* 133:*21* 135:*12*, *20* 136:*2*, *21* 137:*11* 138:*2* 141:*7* 143:*17* 146:*7*, *20*, *23* 147:*4* 150:*20* 152:*1* 154:*18* 156:*1*, *21* 157:*1*, *6* 162:*6* 165:*20* 166:*2*, *11*, *23* 167:*7* 168:*13* 169:*7*, *18*, *19*, *23* 170:*9* 171:*23* 172:*11*, *22* 173:*24* 174:*15*, *23* 175:*15* 176:*19* 177:*22* 178:*6* 179:*1* 180:*18* 183:*23* 187:*15* 191:*4* 203:*3* 210:*24* 214:*3*, *17* 216:*24* 220:*9*, *16* 221:*19* 222:*9*, *19*, *22*, *23*, *24* 223:*3*, *9*, *13*, *16* 224:*4*, *7*, *9* 228:*11*, *12*, *23* 232:*3*, *18* 239:*5* 246:*15* 251:*14*, *19*, *23* 252:*9*, *12*, *18*, *20* 253:*3*, *4*, *5* 254:*17* 256:*1*, *18* 257:*2*, *4*, *7*, *15* 262:*4* 268:*3* 269:*3* 270:*6* 278:*23* 279:*4*, *13*, *18* 280:*14*, *18*, *22* 287:*6* 289:*1* 296:*17* 297:*14*, *22* 299:*19* 300:*6* 310:*8* 315:*14* 316:*7* 323:*6* 325:*21* 332:*16* 333:*1* 344:*19* 345:*4* 348:*21* 350:*15*, *22* 351:*1*, *7* 352:*10* 355:*16*, *17*, *24* 358:*9*, *10* 360:*18* 361:*24* 362:*12*, *13*, *16*, *21* 363:*21* 364:*2*, *17*, *23* 365:*14* 366:*9* 367:*4* 368:*23* 370:*13* 371:*10* 372:*23* 374:*12* 375:*4*, *6*, *15* 379:*9* 381:*22*
enteropathy, 132:*11* 135:*16* 138:*12* 146:*15* 154:*21*
entire 68:*17* 321:*18* 327:*12* 378:*15*
entirely 187:*11*, *12* 223:*20* 348:*19*
entities 230:*1*
Entitled 5:*5* 88:*15*
entity 33:*8* 61:*5* 72:*17* 73:*3* 101:*12* 124:*17* 126:*18* 190:*22* 252:*21* 298:*13* 362:*4* 372:*22* 373:*2* 382:*3*
entry 42:*17*
enumerate 226:*21*
enumerated 82:*17* 90:*15* 226:*7*
enumerating 111:*24*
enumeration 226:*19*
environmental 65:*17*
epidemiologic 50:*22* 75:*16*
epidemiological 50:*13* 58:*23* 59:*6* 87:*10* 242:*4*
epidemiologist 59:*2*
epidemiologists 151:*7*
epidemiology 17:*1*, *3* 58:*21*, *22* 59:*1* 68:*12* 92:*3*
epithelium 127:*15*
Epocrates 325:*4*
equal 259:*24* 260:*11*
esophagogastro duodenoscopy 157:*15*
especially 93:*5* 101:*7* 116:*14* 229:*24* 327:*3*
ESQUIRE 2:*3*, *7*, *12*, *17* 3:*2*
essential 167:*18* 260:*8*
essentially 62:*16* 224:*15*
establish 165:*19*, *24* 166:*9*, *13* 172:*9*
established 75:*1* 77:*24* 92:*2* 142:*24* 143:*6* 146:*11* 217:*1* 257:*16* 258:*15*
establishes 47:*5* 60:*12*
estimation 330:*23*
et 5:*17*, *21* 6:*8* 18:*1* 91:*19* 110:*15* 115:*22*, *24* 146:*15* 201:*1* 256:*2* 271:*13* 281:*13* 282:*7* 287:*10* 371:*6* 375:*3* 377:*22*
ethical 26:*4*
evaluate 18:*3* 265:*18*
evaluated 214:*16* 378:*7*
evaluates 233:*21*
evaluating 148:*17* 378:*11*
evaluation 78:*1* 79:*9* 144:*10* 145:*8* 184:*14* 265:*1*, *2*, *3*

Event 6:*21* 149:*13* 230:*10* 240:*20* 241:*7* 268:*16* 279:*20* 283:*3* 286:*18* 309:*23* 310:*5* 315:*20* 318:*1* 320:*19* 334:*19* 337:*17* 339:*15* 340:*1*, *22* 345:*14* 354:*6*, *13*, *15* 355:*14*, *18* 356:*16*, *17* 358:*8* 382:*6*
events 148:*18* 149:*15* 230:*7*, *12*, *18* 231:*6*, *12*, *17* 233:*13* 303:*11* 322:*8* 354:*24* 359:*4* 380:*21*
eventually 96:*19*
everybody 384:*3*
evidence 47:*4* 60:*11*, *21* 96:*18* 103:*3* 111:*4* 114:*16* 147:*13*, *14*, *21* 149:*16* 151:*17* 153:*13* 166:*20* 168:*1* 174:*9* 206:*10* 209:*1*, *21* 227:*16* 251:*3* 256:*11* 279:*3* 318:*7* 329:*7* 343:*6* 369:*2*, *4*, *9*, *10*, *11* 373:*20* 378:*8*, *11*
evidence-based 16:*24* 150:*4*
evidenced 180:*21*
evinced 218:*13* 325:*24*
evolved 27:*22*
exact 187:*8* 196:*2* 225:*11* 315:*2* 346:*20*
exactly 114:*10* 322:*21* 327:*18*
EXAMINATION 9:*11* 257:*22* 366:*23*
examine 238:*16*
examined 9:*9*
examining 316:*20*
example 17:*2*, *20*, *21*, *24* 18:*7* 19:*6*, *13* 20:*13* 22:*10* 25:*3* 53:*3* 69:*1* 72:*9* 83:*20* 91:*24* 93:*6*, *19* 94:*19* 96:*9*, *14* 97:*22* 98:*5* 103:*17* 112:*11* 119:*1*, *4* 125:*16*, *17* 126:*6* 143:*14* 157:*12* 167:*19* 168:*17*, *20* 170:*20* 171:*1*, *8* 211:*16* 223:*18* 226:*3* 227:*11* 230:*6* 242:*11* 243:*11* 245:*16* 254:*23* 280:*19* 283:*10* 285:*6* 295:*17* 304:*19* 325:*2* 333:*8* 339:*19* 345:*10*, *13* 355:*22*, *23* 356:*2* 361:*4* 365:*19* 371:*11*, *14*, *19* 374:*2* 380:*3*
examples 99:*16*
exceeded 222:*9*
exception 24:*2* 191:*6*
excerpt 335:*19* 336:*3*
Excerpts 6:*16* 335:*11* 338:*16*
exchange 338:*15*
excluded 245:*17*
exclusion 247:*16* 256:*22*
exclusively 169:*24*
excused 384:*4*
exemplify 345:*4*
exercise 113:*1* 126:*16*
exercising 333:*18*
exhaust 131:*3*
exhausted 97:*14*
exhaustive 225:*15* 254:*20*
Exhibit 6:*10*, *14*, *24* 7:*5* 9:*2* 11:*2*, *8* 14:*8*, *18* 28:*7*, *9*, *16* 34:*11*, *19* 35:*3*, *3*, *8*, *22* 36:*5*, *12*, *13*, *15* 37:*18* 38:*1*, *9* 39:*1* 40:*4* 42:*15* 43:*19* 80:*2* 83:*23* 84:*17*, *17* 85:*5* 88:*14*, *24* 89:*9* 90:*16*, *23* 91:*1*, *10* 92:*5* 161:*8* 178:*23* 179:*7* 200:*20* 255:*22* 256:*7*, *17* 262:*12*, *14* 263:*1* 271:*7* 307:*8*, *10*, *17*, *17* 308:*5*, *5*, *10*, *21* 318:*6* 320:*2*, *4*, *11* 335:*10*, *18* 339:*23* 340:*3*, *9*, *13* 343:*5* 345:*21*, *24* 346:*4* 357:*21*, *24*
exhibited 274:*18* 276:*18*
exhibits 34:*22* 35:*2* 36:*8* 44:*1* 300:*13* 301:*10*
existed 95:*15*
existence 61:*12* 62:*17*
existing 33:*17*
exists 114:*12*
expect 380:*8*
expensive 64:*1*
experience 16:*22*, *23* 72:*11* 73:*4* 90:*1*, *12* 95:*10* 114:*22* 125:*9* 183:*8* 184:*6* 200:*3* 279:*14* 288:*24* 289:*6* 296:*15* 323:*11*
experienced 284:*4* 322:*7* 341:*18*
experiment 55:*20* 57:*13*, *23* 226:*23*, *24* 227:*4*
experimental 260:*14*
experimentation 53:*18*
experiments 50:*10*, *13*, *23* 51:*13*, *16*, *22*, *24* 52:*23* 62:*11* 258:*18* 259:*22* 261:*5*, *20*
expert 1:*7* 4:*21* 12:*14* 13:*3* 22:*20*, *23* 23:*2*, *4*, *22* 25:*17* 27:*8*, *10*, *17*, *20* 29:*13* 30:*19*, *24* 31:*7*, *12*, *19*, *21* 32:*4* 33:*2* 34:*12* 61:*8* 62:*20* 86:*10* 87:*16* 90:*18* 91:*13* 98:*22* 99:*20* 100:*3* 163:*15* 275:*18* 302:*24*
expertise 29:*20* 30:*2* 77:*1* 87:*4*
experts 20:*21* 163:*20*
explain 10:*3* 69:*11* 107:*3*, *5*, *6* 372:*2*
explained 103:*1* 255:*7*
explaining 235:*5*
explanation 10:*17* 74:*10* 79:*13* 112:*7* 127:*13* 216:*10* 338:*2* 372:*24*
explanations 334:*8* 344:*6*
explicating 225:*21*
explication 220:*6*
explicit 103:*12* 117:*15*
explicitly 84:*23* 93:*10* 94:*1* 132:*22* 258:*1* 327:*9* 334:*3*
explore 143:*16*
exposed 69:*5* 79:*5* 223:*10* 248:*22*, *23* 249:*3* 266:*14* 276:*23* 277:*16* 281:*1*
exposure 67:*10* 114:*18* 145:*22* 158:*3* 229:*9* 254:*22* 267:*5* 280:*4* 378:*20*
expounded 219:*18*
express 270:*24* 367:*24*

expression 132:*10* 361:*13*
extensive 296:*15*
extensively 261:*13* 262:*6*
extent 51:*12* 86:*23* 87:*21* 215:*17* 260:*1* 291:*23* 303:*7* 305:*20* 380:*6*
extremely 259:*16*
eye 123:*6*, *11*
eyes 185:*23*

< F >
facing 37:*8*
fact 34:*7* 61:*5* 65:*8*, *14* 66:*21* 78:*12* 117:*11* 121:*24* 122:*21* 146:*18* 152:*24* 156:*24* 166:*22* 167:*7* 173:*24* 178:*18* 181:*20* 184:*24* 189:*4* 195:*8*, *9* 203:*9* 246:*10* 248:*21* 251:*6* 261:*24* 270:*7*, *9* 284:*17* 323:*13* 324:*7*, *23* 326:*10* 328:*24* 329:*22*, *24* 334:*5* 341:*22* 342:*6* 343:*23* 344:*2*, *18* 362:*18* 371:*4* 373:*7*, *19*, *22* 377:*11* 379:*14*
factor 250:*23* 254:*13*
factors 65:*17* 68:*21*, *24* 73:*10* 225:*4* 334:*21* 337:*14*, *21* 338:*9*
faculty 58:*24*
failed 215:*4* 216:*1*
failure 383:*15*
Fair 10:*4* 18:*18*, *21* 21:*4* 30:*20* 112:*22* 142:*11* 152:*22* 188:*19* 208:*10* 305:*24*
fairly 24:*22* 96:*1* 164:*23* 349:*20*
fall 314:*1* 383:*6*
familiar 59:*20* 72:*17* 73:*3* 225:*16* 230:*24* 261:*16* 298:*14* 305:*3* 322:*15* 323:*8*
familiarity 59:*23*
family 180:*22* 188:*23* 189:*13*, *15*, *23*
famous 375:*20*
far 42:*23* 66:*21* 202:*18* 220:*4* 222:*9*, *13* 236:*6* 239:*22* 265:*10* 325:*6* 381:*6*
fashion 204:*12*
fat 117:*14* 119:*6*, *14*
fatal 284:*16*
fate 264:*3*
fatty 119:*1*
fax 1:*22*
FDA 12:*15* 161:*12* 162:*6* 228:*2*, *4*, *18* 229:*19* 298:*22* 299:*12* 303:*4*, *9* 304:*4* 356:*15*, *19*, *20*, *21* 357:*4* 359:*4*, *7*
FDA's 228:*14*
feature 116:*22*, *23* 117:*1*, *2* 120:*9* 124:*14* 126:*22* 128:*1* 185:*1* 274:*12* 276:*5* 279:*8*, *10*, *10*, *15*, *18*, *19* 349:*10* 361:*5*, *6*, *7* 362:*21* 364:*5*, *6*, *18*
features 50:*18* 71:*24* 74:*10* 100:*20*, *20*, *21* 101:*1*, *5*, *9* 116:*20* 121:*1* 124:*3*, *3* 141:*3*, *4* 252:*10*, *11* 253:*8* 274:*19* 275:*15*, *20* 276:*2*, *15*, *19*, *21* 277:*18* 278:*22* 279:*1*, *12*, *23* 280:*1*, *12* 366:*9*
February 1:*7* 385:*15*
Fecal 362:*20*, *24* 363:*16*, *17*
feces 361:*5*, *7*
Federally 1:*18* 385:*14*
feel 169:*8* 293:*24*
feeling 255:*10* 303:*10*
feels 169:*15*
Feldman 80:*19* 84:*5* 323:*15* 324:*5*, *6* 332:*13*, *18* 334:*1*
felt 87:*8* 198:*6* 293:*15* 304:*7*
female 345:*17* 347:*1*, *19*
fences 239:*16*
fewer 158:*2* 239:*22*
fibrillation 322:*10* 327:*6*, *8*
field 62:*20* 265:*11* 382:*16*
fight 106:*7*
figure 264:*17*, *18* 287:*21* 296:*2*
figured 190:*14* 191:*3* 294:*3*
files 24:*23*
filings 298:*21*
filled 68:*17*
final 37:*14* 274:*17*
finally 72:*16*
find 20:*20* 22:*5* 56:*19* 62:*18* 105:*21* 106:*17* 138:*18* 140:*8* 144:*15* 159:*22*, *23* 173:*8* 238:*21* 239:*22* 272:*10* 295:*19* 298:*16* 325:*4* 356:*17* 363:*7* 366:*3*
finding 54:*4* 122:*2* 144:*12* 145:*6* 233:*22* 238:*12* 274:*3* 372:*1*
findings 123:*19* 214:*20* 215:*21* 255:*8*, *12* 267:*17* 278:*9* 369:*4*
finds 143:*2*
fine 46:*6*, *23* 76:*23* 92:*18* 104:*3*, *13* 106:*1* 107:*13* 120:*3* 130:*15* 139:*6* 169:*15* 198:*16* 208:*5*, *18* 238:*5* 249:*14* 253:*22* 339:*1* 364:*9*
finish 67:*17* 94:*21* 207:*17*
finished 101:*23* 106:*24* 130:*17* 137:*8* 172:*2* 189:*18* 190:*3* 209:*14*
finishes 318:*19*
firm 145:*24*
first 9:*22* 20:*24* 26:*5* 27:*12*, *15* 29:*8*, *24* 36:*16* 42:*16*, *17*, *21*, *24* 43:*10* 57:*5* 65:*21* 66:*17* 68:*5*, *5* 70:*11*, *14* 77:*11* 80:*18* 82:*19* 93:*6* 97:*21* 106:*11*, *15* 107:*15* 111:*16* 113:*22* 129:*7*, *10*, *18* 138:*18* 147:*11* 152:*13* 163:*9* 184:*13*, *15*, *20* 190:*7* 202:*13*, *15* 203:*7* 213:*6*, *13*, *14* 216:*21* 224:*22* 254:*20* 263:*10* 267:*11* 273:*20* 297:*17* 312:*18* 313:*7* 315:*4* 319:*4* 320:*23* 325:*24* 330:*12* 334:*16* 339:*13* 340:*15* 350:*16*, *17* 358:*17*, *24* 359:*24* 364:*22* 371:*1* 381:*7*, *11*
fit 113:*21* 184:*12* 313:*22*
fits 372:*4*
Five 137:*11* 334:*16*
fivefold 159:*4*, *11*
five-minute 254:*2*
flag 262:*10*
flaw 343:*2*
Floor 2:*3*

Florham 2:*18*
florid 225:*20*
flower 270:*10*
focus 59:*10* 143:*13* 146:*13* 359:*20*
focused 17:*8* 51:*21* 87:*9* 268:*18*
Focusing 36:*15* 144:*6* 275:*11* 313:*10*
folks 129:*2* 141:*4* 189:*13* 190:*6*, *8* 191:*10* 193:*6* 201:*16* 214:*1* 266:*5* 274:*21* 275:*14*, *16* 276:*12* 277:*15* 285:*24* 350:*7*
follow 103:*20* 104:*5* 105:*17* 151:*12*, *22* 186:*17* 353:*9* 374:*5*
followed 24:*24* 25:*1* 151:*8* 180:*1* 251:*24* 314:*6*, *17* 356:*3*
following 110:*24* 283:*14* 284:*8* 383:*5*
follow-on 78:*9* 268:*2*
follows 9:*9* 173:*14*
follow-up 151:*5* 167:*3* 173:*20* 179:*18*, *23* 206:*23* 218:*21*, *21* 220:*14* 281:*23* 287:*2* 321:*19* 377:*12*, *19* 378:*2*
Fonseka 133:*20* 154:*13*
foolish 252:*24*
forceful 112:*11*, *16*, *20*
fore 94:*2* 306:*12*
forefront 98:*6*
foregoing 385:*17*
Forgive 369:*11*
form 16:*5* 124:*9* 181:*13*, *24* 226:*14* 302:*7* 305:*12* 324:*7* 343:*4* 370:*20* 371:*17* 373:*5* 374:*23* 379:*11* 380:*15* 381:*2* 382:*18*
formal 13:*13* 101:*14* 117:*19* 187:*14* 188:*3* 196:*4*, *21* 356:*13*
formally 27:*10*
forming 378:*9*
formulate 77:*12*
formulating 91:*19* 317:*2*
forth 19:*8* 21:*15* 37:*1* 48:*1* 62:*1* 87:*14* 170:*12* 186:*8* 209:*18* 250:*3* 267:*11* 270:*1*, *11*, *14* 282:*21* 293:*6* 332:*19*
forthcoming 41:*18*
fortunate 151:*5*
forward 140:*2*
found 56:*12* 87:*2*, *7* 88:*4* 99:*15* 120:*22* 145:*21* 157:*4*, *23* 200:*5* 214:*7* 239:*17* 240:*11* 247:*21* 261:*8*, *21* 277:*19* 288:*2*
foundation 18:*11* 19:*11* 215:*15* 216:*5* 217:*11* 233:*16* 236:*3*, *11* 249:*24* 298:*24* 299:*4* 342:*21* 360:*12* 380:*15* 382:*18*
foundational 297:*19* 300:*3*
foundations 357:*11*
four 113:*20*, *22* 130:*20* 163:*23* 164:*2* 273:*10* 278:*3* 283:*19* 334:*15* 345:*9*
fourth 273:*15*
frankly 63:*21* 120:*10* 148:*13* 196:*7* 197:*1* 284:*15* 357:*6*
fraught 149:*4* 189:*19*
FREEMAN 2:*1*
frequent 58:*10* 178:*19* 363:*1*
frequently 58:*8* 191:*19* 241:*14* 304:*20* 314:*24*
friendly 305:*18*
front 36:*4* 38:*8*, *24* 40:*3* 83:*23* 88:*23* 103:*7* 105:*13* 179:*14* 256:*6*, *17* 262:*24* 272:*24* 291:*18* 307:*17* 327:*14* 340:*13* 357:*3*
frustrated 304:*5*
fuel 316:*4*
full 20:*19* 147:*11* 180:*16* 182:*16* 184:*20* 199:*21* 216:*21* 224:*22* 315:*24* 319:*4* 339:*13* 340:*15*
fully 90:*10* 106:*23* 215:*9* 355:*21*
function 30:*19*
functioning 32:*4*
further 46:*1* 76:*16* 94:*4* 96:*19* 107:*3* 113:*5* 150:*11* 182:*8* 200:*11* 218:*17*, *17* 219:*18* 220:*6* 246:*21* 251:*11* 338:*1* 344:*18*
future 116:*13* 146:*13*

< G >

gain 127:*20*
game 68:*15*, *16*
gastroenteritis 69:*6*
gastroenterologist 58:*4*, *5* 368:*15*
gastroenterologists 72:*14*
gastroenterology 18:*5* 57:*10* 136:*17*
gastroenteropathy 364:*5*

Gastrointestinal 18:*4* 120:*15* 349:*9* 350:*9* 363:*2*, *18* 364:*8*
gender 269:*21*
General 3:*2* 4:*24* 28:*5* 32:*13* 34:*14* 39:*10* 44:*2*, *3*, *11*, *24* 78:*21* 134:*16* 148:*22* 149:*20* 163:*16* 190:*13* 191:*6* 225:*7* 242:*3* 270:*3* 272:*21* 299:*13*, *24* 327:*23* 354:*9*, *16* 357:*2*, *13* 381:*6*
generalize 95:*3*
generalized 315:*6*
generally 26:*15* 147:*12* 148:*1* 211:*22* 240:*9* 251:*23* 277:*16* 327:*5*
generate 24:*17*, *18* 25:*11* 36:*19* 92:*11* 164:*15* 316:*17* 328:*17* 354:*12* 355:*17*
generated 16:*1* 25:*12* 34:*21* 93:*2* 95:*22* 98:*20* 137:*5* 310:*3* 357:*8* 367:*12*
generates 301:*4*
generating 25:*10* 40:*14*, *20*, *24* 41:*9* 42:*1*, *7* 45:*13* 93:*9* 163:*20*
generation 40:*17* 41:*19* 164:*17*
generic 148:*3* 149:*9* 150:*3* 211:*14* 242:*6* 325:*18* 373:*20*
Generically 354:*4*
genes 211:*19*
genetic 212:*3*
gentlemen 80:*8*
getting 52:*13* 72:*7* 111:*7* 119:*24* 120:*12* 167:*22* 185:*23*

193:4 195:2, 8 248:4 290:21 357:5
GI 114:23 141:12, 14 143:9 190:6 315:1, 3, 6 325:18
give 17:19, 21 30:6 80:8 96:8 106:16 107:5 132:13 134:13 190:10, 22 196:2 203:4 219:4 272:9 283:10 319:22 321:1 330:15, 22 332:10 334:24 341:4 348:5 372:23
given 64:1 103:6 113:3, 17 199:23 200:1 210:22 222:14 249:4 269:2 281:1, 12 295:17 298:12 311:11 356:17, 20 362:16 363:3 364:16, 22 372:5 381:21 385:6
gives 139:7
glad 163:13 353:8
glancing 272:7
glean 242:22
gleaned 151:18
global 334:17
globally 349:10
gluten 68:1, 5, 10 73:11 78:22 79:5, 5 168:6, 11, 15 169:2, 14 176:14, 16 180:22 189:9 197:7, 9, 16 255:10 290:8 296:18 343:22 361:23
gluten-containing 78:15
gluten-free 167:22 168:21 211:13 212:7 281:2, 5, 10, 14 290:10
gluten-induced 168:13 169:7
go 26:4 46:21 73:14 78:18 79:24 81:19, 23 86:13 93:17 94:16, 20 105:22 106:6 107:14 108:4 115:18 118:10 132:20 137:9 139:15 160:20 178:4 182:14 207:21 208:4 212:21 214:21 236:15 255:16 259:1 266:12 268:13 277:23 292:17 303:11 304:14 305:8 316:23 319:10 325:12 336:8 339:1 353:15 361:1 370:15, 24 372:15 376:8
goal 342:5
goes 75:2 159:2 167:23 362:7 364:7 369:1, 13
going 13:17 17:6 18:16 26:10 28:4 32:16 33:10 45:24 49:14 72:13 83:22 86:13 105:12, 19, 20 106:10, 22 126:13 139:16 140:2 157:20 188:6 192:18 196:9 199:3 208:12, 13, 19 219:3 248:10 250:16 252:3 255:17 271:3 277:22 302:19 306:20 307:3 324:14 326:16 327:11, 12 338:21 343:23 345:20 346:17 353:6 357:20 358:15 366:13 372:8, 15 383:4, 7, 11
gold 148:9
GOLKOW 1:22
Good 9:14, 15 39:16 105:3 140:1, 4 195:23 262:8 264:17 294:5 301:22 382:4
gotta 79:23 318:14, 16, 19
gotten 195:14
gradient 224:15
gradually 285:12
granted 95:6 99:11 108:7 132:8 138:21 139:1
granting 25:21
grave 151:9
great 73:4 118:16 145:12 363:10
Green 57:7 109:13 110:5 153:11 184:21 187:7, 23 198:2 202:16 204:2 214:19 215:3, 20, 24 263:4 271:5 349:2, 23
Greywoode 6:3 140:18 145:4 146:2, 3 156:9, 10, 13, 15, 17, 18 236:21, 23 237:21 238:15 262:12, 20 263:2 371:22 378:23
group 115:3 129:1 145:23 178:18 183:11, 15 201:23 202:13 203:21 204:20 220:22 240:9 246:14 249:1, 2 267:6 273:3, 6, 9, 12, 14, 15 274:10 275:7, 9, 24 276:6, 22 381:15
groups 184:1 244:23 247:3 249:6, 10 273:10 274:23
grow 168:24
guess 78:8 121:23 199:20 235:18 334:14 368:1 383:20
Gujral 98:17
gut 69:3 127:15

< H >
habit 361:9, 10, 11
half 70:15 223:18
half-life 176:2, 21 294:23
Haller 233:3
halted 230:16
Hammoudi 137:24 155:13, 14
hand 28:3 48:8 149:12 150:15 308:21 347:6
handed 12:18 28:15 34:18 179:6
handful 344:14
handing 320:10 335:17
handled 372:14
handy 305:18
Hang 321:7
haplotype 211:18
happen 49:14 68:6 315:7 351:8 363:24
happened 246:4, 17 281:23 282:4, 10, 18 308:15 315:3 338:15 351:16 381:6, 11
happening 230:10
happens 69:7 235:19 247:19 314:24
happy 64:19
hard 175:19 280:6
harder 251:15
hard-pressed 171:7
harmed 60:7
Hartranft 138:9 155:17
Hasebe 6:19 81:6, 8 334:17 335:13, 20 337:20 338:1
Hasebe's 336:23
hat 357:4
HCT 191:23 341:2
head 10:12 188:18 190:12 334:17 366:4

heading 182:*15* 226:*17* 227:*4* 297:*13*
headlined 138:*22*
heads 129:*15* 188:*1*
heal 375:*12*
healing 183:*5* 296:*14*, *20* 375:*10*
Health 59:*2* 161:*12* 162:*9* 164:*6*
healthcare 151:*10* 171:*13*
hear 311:*22* 324:*23*
heard 185:*15*, *19* 196:*22* 303:*8*
hearing 184:*21*
heart 101:*6*, *8*, *10*
height 123:*24*
HeLa 261:*16*
held 1:*15*
help 45:*19* 163:*13* 198:*7* 212:*24*
helped 272:*14* 382:*24*
helpful 60:*2*, *3* 87:*7* 88:*6* 91:*21*, *23* 98:*2* 119:*18* 152:*4* 242:*12* 261:*21* 266:*11* 290:*6* 297:*20* 300:*4* 302:*15* 356:*1* 364:*12* 373:*2*, *12*, *19* 382:*14* 383:*16*
hero 164:*6*
herring 328:*1*
Herve 81:*16* 86:*6* 353:*21*
hesitant 121:*17* 124:*18* 142:*1* 144:*18* 190:*10* 197:*7* 285:*17*
hesitate 188:*17*
hesitates 268:*10*
Hey 39:*18*
Hideki 81:*12* 84:*11*
hierarchy 147:*13*, *20* 148:*1*, *2*, *3*, *5*, *13*, *22* 149:*10*, *16*, *21*, *23* 150:*3* 372:*18*
high 285:*11*, *12* 351:*4* 374:*3*
higher 114:*15* 221:*18* 223:*2* 224:*3* 229:*14*
high-impact 370:*1*
highly 154:*11*
high-reputation 370:*2*
Hill 224:*16*, *18*, *24* 225:*5*, *9*, *17*, *21*, *23* 226:*4*, *6*, *17*, *20* 227:*1*, *9* 241:*9*, *13* 254:*11* 378:*6*
Hinman 80:*22* 81:*5* 85:*24*
hint 98:*2*
histologic 50:*7*, *19*, *21* 51:*10* 53:*23* 54:*3* 69:*23* 74:*3*, *5* 96:*17* 111:*2* 153:*13* 167:*12* 168:*1* 192:*20* 255:*12* 257:*5* 290:*4*, *22* 291:*1*, *5*
histological 74:*3* 100:*19* 255:*8* 296:*5*
Histologically 74:*8* 245:*19* 280:*10* 291:*11*, *22* 292:*2*
histology 6:*5* 53:*7* 109:*24* 237:*12* 271:*9* 290:*13* 292:*6*
histopathologic 88:*8*
histopathologic al 87:*6* 253:*14* 273:*24* 274:*3*
history 180:*23* 188:*23* 189:*13*, *15*, *23* 193:*17* 257:*23* 283:*19* 322:*10* 326:*11*
HLA-DQ2 211:*18*
Ho 81:*24* 86:*3* 307:*20* 308:*22* 309:*1* 333:*8*
hoc 62:*10* 374:*13*
hold 174:*6* 233:*19*
holiday 287:*22* 288:*5*, *8*, *9*, *10*, *19* 289:*7*, *19*, *22* 292:*11*, *12*, *16*, *24*, *24* 293:*9* 294:*8*, *21* 295:*15*, *15* 330:*7*, *24* 331:*4*, *11*, *16*, *23* 332:*11*
holidays 288:*14*
homogeneous 129:*17*, *17*
honest 171:*11*
honestly 25:*19* 54:*19* 122:*12*
hoops 199:*6*
hope 26:*6* 265:*21*
hopefully 301:*5*
Ho's 308:*6*, *11*, *13*
hospitalization 116:*3* 285:*8* 334:*23*
hospitalizations 293:*18* 337:*16* 382:*1*
hospitalized 284:*6* 285:*7*
hour 43:*21* 372:*15*
huge 239:*13* 268:*24* 269:*16*
human 60:*6* 259:*16*
humans 59:*19*
hundred 157:*18* 191:*5*
hung 119:*24*
Hutfless 164:*3*
hydrochlorothiazide 191:*22*
hypermotility 363:*18*
hypotension 284:*7*
hypothesis 145:*7*, *18* 270:*15*
hypothesized 66:*9*
hypothetical 70:*11*

< I >

i.e 192:*24* 332:*8*
iceberg 143:*19* 239:*9* 360:*8*, *15* 363:*7*
idea 61:*11* 208:*15* 267:*8*
ideal 100:*23* 260:*10*
ideally 304:*7*
ideas 91:*22*
identical 194:*8* 221:*3* 259:*3*, *21* 260:*8*
identification 9:*5* 14:*14* 28:*12* 34:*15* 36:*1* 38:*5* 88:*20* 179:*3* 201:*2* 256:*3* 262:*21* 271:*14* 307:*13* 320:*7* 335:*14* 340:*6* 346:*7* 358:*2*
identified 15:*19* 19:*6* 79:*15* 83:*16* 84:*10*, *21* 86:*19* 90:*14* 92:*5* 237:*22* 255:*9* 288:*9* 350:*17*
identifies 91:*11*
identify 58:*3* 80:*15*, *19*, *22* 81:*12* 84:*4* 86:*9* 96:*6* 105:*5* 106:*11* 107:*2* 113:*19* 114:*1* 136:*24* 152:*6* 161:*10* 163:*14* 225:*14* 226:*9* 282:*22* 283:*5*, *6* 287:*1* 319:*5* 338:*10* 354:*14*, *24* 355:*9*, *12* 360:*7* 370:*17*, *23*
identifying 372:*21*
ill 142:*1* 166:*17* 169:*3*, *4* 183:*1* 195:*11*, *16* 255:*10* 284:*18*, *22* 327:*3*
ill-defined 124:*17*
illness 285:*5* 288:*21* 296:*6* 323:*19* 324:*2*

325:16 332:15 334:7
illustrated 288:11
illustrative 99:7 287:20 345:3
imagine 142:5, 17 169:11 301:1, 6
imaging 97:18
immediate 16:20
immediately 21:11 344:5, 20
immune 67:5 69:4 259:11
Immunopathogenesis 5:18 135:14 154:20 254:16 255:24
immunosuppressant 193:16 246:3
immunosuppressants 192:9, 11 193:6 194:13 205:23 206:2, 6, 19 248:24 249:5
immunosuppression 193:2 194:5 243:10, 21 245:7 246:12, 19 247:1, 4, 15 248:16, 19
immunosuppression's 250:6
immunosuppressive 377:21
impact 262:3
impacted 157:11
implicated 325:20
implication 284:15
implications 268:11
implicitly 318:2
implied 132:23 133:10, 16, 17, 18
imply 139:2, 2, 10
implying 282:7
import 139:12
importance 149:17
important 241:11 259:23 292:1 301:11, 15 302:3 343:16 352:15, 19 360:11 364:15 365:4 372:3
imposed 281:15
impractical 151:17
impression 178:20 189:2 316:21 373:15
imprimatur 234:4
improve 78:5 183:11, 16, 18 215:4 216:2
improved 182:21 200:4 202:4 206:20 221:8, 14 245:18 283:14 293:15 377:20
improvement 111:2 167:24 175:13 176:7 177:1 193:19 195:6, 22 205:21 206:1, 5, 10 209:2, 21 210:7 216:9 218:14, 23 220:11 243:18 247:14, 15 284:5 289:2, 23 290:12, 13, 17 293:11 295:3 296:21 369:5 375:24 376:5, 19 377:6
improvements 187:2
inaccurate 160:17 181:10, 17
inaccurately 272:9
inadequately 101:18
inadvertent 163:9
incidence 64:3 270:6 353:3
incident 71:1
include 15:18 16:17 17:16 36:23 154:22 184:7 247:11 248:11 257:23 304:21 364:7, 10 366:10 369:16, 24 375:11 383:7
included 75:3, 4 77:23 78:2 79:9 85:1 93:15 99:18 186:10 206:7 225:23, 24 256:24 257:17 298:21 300:13, 14 353:2, 19 368:10 369:18
includes 15:14 50:18 283:4 287:8 335:21 336:4 369:3
including 24:5 72:14 87:16 89:10 91:13 121:2 253:13 305:14 349:19
inclusion 77:19, 22 128:9, 10 183:15 184:12 245:14 246:9, 11 247:6 248:14 257:14 313:22 348:15
inclusive 247:13 360:22
incomplete 80:6 309:21 314:9
inconsistent 313:12
incontinence 362:20
incorporate 306:16
incorporates 369:22
increase 159:11 224:2
increased 93:20 159:4 224:2 363:16
increasing 221:17
increasingly 61:6 64:3 132:7
INDEX 8:2 104:12
indicate 10:2 59:13 146:10 206:4 221:24 274:17 278:14 287:11, 16 311:12 326:20 327:23 330:6 341:17 352:23
indicated 206:22 219:18 240:6 343:12 351:11 376:21
indicates 61:21 146:16 184:10 211:11, 15 218:18 287:21 310:18 330:1, 11, 13 334:8
Indicating 81:1 133:6 220:8 347:12 376:12, 13
indication 265:11 325:14 327:16 331:3
indirectly 306:18
individual 70:2, 4, 24 71:6, 14 120:5 149:4, 8 223:8, 10 302:1
individuals 62:22 63:4, 12 69:13, 19, 21 70:7 73:13 108:17 117:9 120:23 157:23 163:23 178:14 260:6
individual's 375:11
induce 108:20 115:13 127:18
induce, 103:13
induced 116:12 138:8
induces 50:20
inducing 224:6
induction 67:13
infarction 101:11
infection 171:2
infer 331:9
inflammation 59:14 364:8
inflammatory 177:19
inform 185:24
informal 204:7
INFORMATION 1:7 88:7 91:12 110:17 199:23 200:1 242:12 297:20 300:4 321:20, 24 329:16, 19, 21 330:1 380:1, 7, 9 381:17 382:8
informed 75:20 114:20

infusion 294:*15*
ingredients 192:*1*
initial 93:*16* 106:*9* 110:*9* 122:*5* 133:*5* 178:*20* 183:*20* 185:*16* 212:*21* 233:*22* 247:*11* 248:*11* 314:*2* 349:*15*
initially 27:*8* 33:*6* 74:*13*, *20* 75:*8*, *14*, *21* 93:*2* 104:*9* 174:*13* 203:*10* 212:*8*, *17* 213:*18* 214:*5* 224:*23* 228:*24* 239:*24* 246:*18* 365:*14*
initiate 183:*3*
initiated 287:*13* 294:*7*
initiating 367:*5*
initiation 315:*11*
initiative 120:*21*
injured 127:*15*
injury 23:*19*, *24* 119:*4*
input 13:*16* 357:*9*
inputs 317:*6*
inside 129:*15* 356:*19*
instance 132:*20* 141:*21* 174:*8* 222:*3* 288:*8* 303:*19* 333:*8*
instances 65:*15*, *20* 66:*18*, *20* 168:*3* 170:*20* 354:*14*
institution 73:*1* 199:*1*
instruct 46:*5*
instructions 9:*22*
insufficiency 383:*14*
insufficient 123:*17* 126:*8*
intend 47:*14*, *24* 48:*10*
intended 239:*24* 286:*2*
intentional 342:*6*
intentionally 342:*1*, *4*
interacted 58:*15*
interactions 58:*10* 304:*17*
interchangeability 212:*11*
interchangeable 362:*2*
interchangeably 252:*4*
interest 339:*8* 353:*12* 382:*15* 383:*4*, *10*
interested 32:*22* 144:*1* 162:*5* 186:*14* 218:*1* 238:*7* 267:*4*
interesting 74:*17*
intermittent 128:*20* 327:*7*
intermittently 71:*11*
Internal 107:*17* 136:*6* 297:*13*, *18* 298:*1*, *6*, *19* 299:*7*, *18* 300:*2*, *15* 368:*17* 370:*4* 374:*18* 379:*23* 380:*9*, *18*, *22*
internally 351:*20* 380:*7*
international 116:*10*
interobserver 125:*5*
interpret 133:*5*
interpretation 128:*21* 159:*5*, *6* 183:*14*, *21*, *24* 184:*4* 202:*2* 218:*11* 328:*14*
interpreted 125:*11*
interprets 332:*22*
interrupt 175:*4* 207:*3*, *16* 342:*22*
interval 158:*5*, *14*, *17* 159:*1*, *7*
intervention 171:*4*, *19* 230:*15*
interventions 148:*15*
interviews 264:*16*
intestinal 50:*7* 114:*17* 121:*5* 134:*6* 231:*12* 233:*4* 262:*7* 296:*19* 363:*9*, *11* 364:*9* 368:*23*
intestinal-related 231:*6*, *17* 233:*13*
intestine 59:*15* 123:*5* 261:*8* 262:*2*, *4*
intimately 21:*1*
introduce 202:*21*
introduced 68:*6* 327:*19*
introduction 108:*22*
invariable 165:*10*
investigate 49:*6* 62:*8*, *13* 63:*20* 64:*7* 169:*5*
investigated 50:*2* 53:*23*
investigation 75:*4* 78:*2* 257:*17*, *18*
investigations 79:*10*
investigator 164:*10*
investigators 115:*4* 244:*23* 246:*13* 258:*22* 259:*20* 286:*1*
invite 161:*17*
Invoice 4:*21* 28:*10*, *20* 29:*1* 42:*16* 82:*19*, *23* 83:*7*, *17*, *21* 84:*2*, *9*, *17* 85:*5*, *23*
invoiced 85:*1*
Invoices 5:*3* 12:*19*, *21* 28:*18* 38:*3*, *11* 39:*2* 40:*5*, *8*, *12*, *18*, *22* 41:*5*, *17*, *18* 42:*2* 82:*17* 83:*11* 85:*19* 86:*5*
involved 24:*23* 25:*22* 56:*13* 167:*10* 202:*22* 203:*16*, *20* 236:*1* 284:*18*
involves 167:*13*, *15* 257:*22*
involving 27:*7* 370:*6*
iron 119:*9*, *11* 121:*2*
irrelevant 98:*24*
issue 26:*16*, *20*, *21* 50:*24* 63:*16* 98:*23* 114:*6* 149:*11* 150:*14* 160:*16* 199:*8* 243:*15* 244:*11* 264:*7*, *23* 285:*13* 306:*10* 360:*23* 362:*11* 370:*5*
issued 11:*4*
it, 377:*22*
item 133:*23* 163:*6*
items 11:*21* 12:*1* 15:*14*, *18* 90:*15* 91:*12* 358:*18*, *19*, *23*
iteration 36:*17*
It'll 105:*24* 106:*1*
its 53:*12* 96:*20* 98:*13* 137:*7* 143:*2* 146:*17* 228:*5* 251:*13*, *13* 252:*10* 275:*6* 328:*21* 329:*23* 356:*16* 364:*18*

< J >

January 53:*12* 97:*23* 332:*2*, *4*
Japan 334:*18*
Jeffrey 81:*14*
JERSEY 1:*2* 2:*4*, *18*
JESSICA 2:*17*
jessica.brennan@dbr.com 2:*19*
Joe 187:*24*
jogged 98:*10*
joke 292:*17*
journal 18:*5* 53:*11* 57:*9* 136:*16* 154:*12* 370:*2*, *3*
JS 1:*6*
judgment 333:*19*
Julian 93:*19*
July 161:*13* 339:*16* 340:*23*
jump 208:*14*

jumping 323:*10*
jury 76:*18, 19*
jury's 76:*14*

< K >
Kaplan 1:*16* 2:*7*
KATZ 2:*1*
keenly 186:*16*
keep 10:*11, 16* 140:*2* 187:*13* 188:*12* 317:*19* 363:*8*
keeping 187:*14* 188:*2* 195:*1* 363:*22*
Ken 9:*16* 207:*15*
KENNETH 2:*12*
kenneth.murphy@dbr.com 2:*15*
kept 188:*21*
KESSLER 2:*7* 164:*3, 5*
Kessler's 102:*15, 17*
Kim 48:*20* 54:*10* 66:*11* 173:*9* 207:*22* 312:*5*
Kimberly 1:*17* 385:*13*
kind 10:*14* 18:*15* 25:*6* 159:*10* 223:*5* 232:*15* 245:*21* 257:*21* 265:*14* 269:*11, 14* 285:*3* 325:*7* 326:*10* 345:*3* 354:*17* 360:*18*
kindly 270:*17*
kinds 359:*23*
kitchens 197:*11*
Klug 3:*2*
knew 33:*17* 73:*2* 97:*15* 164:*7* 269:*18* 330:*2* 344:*3*
know 13:*23* 14:*23* 18:*20* 26:*15* 39:*7* 46:*12* 49:*12* 54:*12* 55:*4* 64:*2, 18* 66:*21* 67:*18* 68:*23* 70:*10* 71:*22* 73:*7* 77:*15* 82:*3* 96:*2* 118:*5* 119:*6, 7* 121:*20* 125:*21* 127:*14, 19* 144:*7* 145:*15, 20* 147:*5* 150:*24* 157:*19* 158:*6* 169:*22* 181:*19* 182:*5* 188:*16* 190:*18, 20, 22* 192:*3, 5* 194:*2* 196:*18, 23* 204:*8* 207:*19* 208:*11, 13* 213:*21* 218:*1* 222:*11* 239:*6, 10, 12* 257:*10, 13* 258:*14, 23* 259:*10* 269:*2, 16, 24* 279:*5* 288:*18, 23* 291:*13* 295:*18* 296:*4* 312:*2* 317:*22* 326:*18* 327:*2* 343:*1* 344:*9* 347:*2* 352:*5, 7* 353:*12* 357:*1* 362:*16* 364:*16* 372:*8* 381:*9* 382:*11*
knowing 189:*22*
knowledge 63:*18* 64:*24* 95:*5, 8* 99:*12* 162:*4* 177:*22* 224:*10* 231:*11* 352:*1, 9*
known 123:*23* 164:*5* 191:*19* 204:*4* 223:*8, 15* 252:*21* 325:*15* 333:*11* 382:*2*

< L >
label 126:*19* 211:*22*
labeled 212:*17* 213:*18* 214:*6*
laboratory 69:*23* 253:*15* 290:*4*
lack 64:*24* 177:*21* 215:*14* 216:*4, 8* 217:*10* 233:*15* 236:*2, 10* 249:*23* 251:*15* 298:*23* 299:*3* 377:*12* 378:*2* 380:*15* 382:*18*
lacks 110:*16*
Lagana 6:*8* 53:*3, 17* 86:*10* 96:*14* 102:*4* 110:*3* 112:*18* 131:*18* 153:*5, 9, 10* 237:*2, 21* 238:*6* 271:*3, 13, 20*
Lagana's 86:*20* 87:*3, 13, 17, 17, 22* 88:*5* 89:*12* 102:*21*
laid 370:*6*
land 230:*11*
language 111:*14* 370:*5*
large 56:*19* 60:*5* 120:*23* 239:*17* 242:*23* 244:*14* 261:*8, 15* 262:*2* 301:*2*
largely 87:*2* 202:*1*
larger 305:*22*
largest 276:*20* 277:*12*
lasted 288:*14*
lasting 218:*23*
late 37:*9, 10* 42:*8, 13* 44:*9* 72:*3*
latency 229:*10*
laugh 326:*6*
law 1:*15*
LAWYER'S 386:*1*
lay 352:*11*
layer 278:*18*
lead 120:*15* 315:*18* 353:*9*
leads 221:*18* 224:*3*
learn 202:*7* 270:*4*
learned 17:*4* 21:*3* 123:*4* 202:*20*
learning 64:*3*
leave 329:*11*
LEBWOHL 1:*15* 4:*5, 14, 19, 21, 23* 5:*4, 9* 9:*4, 7, 14* 10:*22* 14:*12* 15:*4* 18:*1* 22:*19* 28:*11, 15* 34:*13* 38:*3* 48:*10* 59:*12* 61:*20* 88:*19* 89:*2* 103:*8* 108:*23* 109:*13* 110:*5* 112:*19* 131:*15* 153:*10* 164:*24* 198:*23* 333:*3* 358:*7* 385:*8*
Lebwohl-1 4:*12* 9:*3*
Lebwohl-10 5:*18* 255:*23*
Lebwohl-11 5:*22* 262:*15*
Lebwohl-12 6:*4* 271:*8*
Lebwohl-13 6:*8* 307:*9*
Lebwohl-14 6:*12* 320:*3*
Lebwohl-15 6:*16* 335:*11*
Lebwohl-16 6:*19* 339:*24*
Lebwohl-17 7:*3* 346:*1*
Lebwohl-18 7:*7* 358:*1*
Lebwohl-2 4:*16* 14:*9*
Lebwohl-3 4:*21* 28:*10*
Lebwohl-4 4:*21* 34:*12*
Lebwohl-5 5:*1* 35:*23*
Lebwohl-6 5:*1* 38:*2*
Lebwohl-7 5:*5* 88:*15*
Lebwohl-8 5:*10* 178:*24*
Lebwohl-9 5:*12* 200:*21*
Lebwohl's 13:*2*
Leffler 102:*6* 164:*9, 17*
Leffler's 102:*20*
left 132:*11* 163:*9* 182:*14* 303:*10* 304:*10* 356:*5* 365:*9*
legal 12:*9* 26:*3* 77:*1*
legitimate 26:*2*
legs 254:*5*
lends 251:*11*
length 132:*2* 331:*16, 21*
lesions 138:*3*
lesser 93:*21* 122:*8*
Lethargic 126:*5, 7, 9*